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The role of standardization at the interface of product and process development in biotechnology

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Abstract R&D stands for Research and Development and while research is essential for new product development in biotechnology, the development and its integration with research (the transfer from research to development) is underexplored. Without efficient and successful process development, biotech companies would not sustain in the long run as process development is a necessary condition en route to industrial commercialization. Based on qualitative interviews with 31 biotech companies and experts, we test a framework with technological, operational and organizational boundary conditions influencing the transfer between product and process development. Our results uncover two additional dimensions: relational and market determinants. We further identify uncertainties in the transfer and investigate if standardization can mitigate these uncertainties and eventually facilitate the integration of product and process development. We find that standardization is a beneficial mechanism for successful integration of the front end of process development activities. The present investigation contributes to the understanding of standards as a knowledge and technology transfer instrument for complex and critical development activities.

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1 Introduction

"Companies that don't innovate die" (Chesbrough 2003, p. xvii). However, inventive talent on its own is not enough to maintain a competitive advantage. Only those who are capable of transforming discoveries and prototypes from the scientific laboratories into marketable products will capture the profits from their innovation. Every year, billions of dollars are spent on process innovation in manufacturing (Malone 1987). The most important challenge many firms face is not only the design of a new product but also conceptualizing, implementing and replicating an accompanying new process within the firm's operating boundaries (Pisano 1996). A good example here is Tesla which has come up with the affordable model 3—their first electric car aimed towards the mass market for a starting price of 35,000 USD. To enter this market with 500,000 pre-orders, the production needs to significantly scale-up which has caused quite some difficult for Tesla.[1] Following this line of thought, the new product development (NPD) literature commonly differentiates between product development and process development (Brown and Eisenhardt 1995). While product development refers to the design or discovery of new products (upstream activities), process development is concerned with manufacturability of these new designs or discoveries (downstream activities). The engineering literature acknowledges efficient transfer or integration of development activities as critical success factors in NPD (Gerwin and Barrowman 2002).[2] However, prior innovation management and technology transfer literature mainly focus on product development, whereas accompanying process development is underexplored (Lu and Botha 2006). For example, Lu and Botha (2006) describe the phenomenon as follows: "All too often priority is given to product R&D, the specifications are then 'thrown over the wall' to manufacturing engineering […] essentially squeezing out any process development time" (p. 2978). Additionally, existing models and studies of process development within innovation management research (Ulrich and Eppinger 2004) do not address the interdependencies of process development with product development. Hence, prior literature hence lacks a holistic picture of product-process integration which can be further enriched by existing studies in engineering and operations management (see footnote 2).

Particularly radical product or process innovations in industries such as pharmaceuticals, chemicals, biotechnology, semiconductors, and advanced materials tend to follow closely related life cycles and changes in process technology can have a substantial impact on product characteristics (Ettlie et al. 1984; Tushman and Anderson 1986; Anderson and Tushman 1990; Ettlie and Reza 1992). In turn, major changes in product design can require

[1] http://www.businessinsider.de/tesla-model-3-production-battery-problems-troubling-2017-11?r=US&IR=T (accessed on November, 5th 2017).

[2] Taking a very technical lens, the engineering literature has investigated "concurrent engineering" or "design–manufacturing system integration" which has been "recognized as a practice of concurrently designing both the product and its downstream production and support processes in the early stages of design to shorten product development time, increase product and process quality, and lower the cost of production" (King and Majchrzak 1996, p. 189). Also based on engineering, the Integrated Product Development (IPD) literature recognizes IPD as the critical paradigm for NPD and is defined by an "overlap and interaction between activities in the new product development process" (Gerwin and Barrowman 2002, p. 938).

a substantial modification of relevant processes. In these industries, process development capabilities and an integration of product-process development are crucial determinants of overall product development performance and productivity (Ettlie and Reza 1992; Pisano 1996).

Particularly research has largely concentrated on understanding the interplay between product and process development in the context of large pharmaceuticals (Pisano 1994). Large pharma companies moving towards an operating model where research is outsourced to biotech start-ups will further enforce the importance of integration efforts between product and process development. In contrast to chemical synthesis, researchers in biotechnology process development often describe their endeavors as 'more art than science' (Pisano 1996, p. 92). Particularly, process developers in biotechnology cannot account for hundreds of years of accumulated expertise and thus only have little theory to guide them in searching for and selecting alternatives. Furthermore, discontinuities evolve when the product side uses different development tools such as different assays, cultivation systems, or quality testing methods than the process side without synchronizing with each other. Severe resource constraints are another challenge especially among young biotech start-ups. Moreover, processes or routines hardly exist; biotech firms rather apply a 'trial-and-error' method for process development due to extremely complex compounds they develop leading to slower and more iterative feedback loops (Pisano 1994).

Hence, this study aims to test firm-internal determinants influencing the transfer between product and process development. We further identify uncertainties inherent to this transfer interface and explore whether and to what extent standardization—a set of focused, disciplined, rigorous practices designed to concentrate efforts[3] (ISO/IEC 2004; CEN 2010)—can help to mitigate these uncertainties and thereby facilitate successful integration of product design and process development (Ettlie and Reza 1992; Ettlie 1995). Standardized, comprehensive datasheets and processes are widely used in the electrical, mechanical, structural and other engineering disciplines. These help engineers to quickly determine whether the behavior of a device will meet the requirements of a system in which the device might be used. Using rigorous standardization to reduce variation, thereby creating both flexibility and predictable outcomes are particularly useful when a prototype needs to be quickly scaled up to serial production. In contrast to pharmaceuticals—where experienced chemical engineers quickly develop routines to test and generate new production processes—biotechnology requires a much greater emphasis on learning-by-doing in the factory (Pisano 1996) due to the apparent complexity of living systems. Hence standardized procedures are more difficult to develop and implement (Canton et al. 2008). Based on a detailed study of 31 organizations active in biotech, we investigate the boundary conditions and uncertainties such as high attrition rates limiting the success of product-process transfer.

[3] According to EU-Regulation No 1025/2012 standard means a technical specification, adopted by a recognized standardization body, for repeated or continuous application, with which compliance is not compulsory. CEN, the European Committee for Standardisation, publishes the following definition: A standard is a technical document designed to be used as a rule, guideline or definition. It is a consensus-built, repeatable way of doing something. Standards are created by bringing together all interested parties such as manufacturers, consumers and regulators of a particular material, product, process or service. All parties benefit from standardization through increased product safety and quality as well as lower transaction costs and prices (https://www.cen.eu/work/ENdev/whatisEN/Pages/default.aspx, accessed on November, 5th 2017). According to the ISO/IEC Guide 2.2004, standardization is an "activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context".

This paper makes two major contributions: First, we identify relational and market determinants as further determinants for successful product to process development transfer. Second, this paper detects standardization as an important coping mechanism for successful integration of product and process development in biotech. Hence, standards are an important transfer instrument for complex and crucial development activities.

The aim of this paper is to answer three fundamental questions: What are the boundary conditions and uncertainties related to the transfer between product and process development? Does product and process development happen sequentially or in parallel? How can the transition from product to process development be facilitated with the help of standardization? The paper is organized as follows: In the first section, we examine the foundations of process development. Following these results, we develop a conceptual framework about the interface between product and process development and its boundary conditions. Next, different types of uncertainties with regard to the interface between product development and process development are discussed and compared. Finally, we present standardization as a mechanism for successful product and process development integration. We then provide a description of our data and methods followed by our results and conclusions.

2 Literature review and theoretical background

2.1 The boundary conditions of process development

Integration and interdependencies of product-process development efforts have widely been acknowledged as crucial critical success factors in NPD (Gerwin and Barrowman 2002). Nonetheless, the beginning of product development has commonly been coined as 'fuzzy' due to its ill-defined starting point which renders successful product-process transfer difficult. Several qualitative studies have examined the influencing factors at this critical stage (Khurana and Rosenthal 1998; Montoya-Weiss and O'Driscoll 2000). The front end of product development is mainly characterized by its experimental work, high uncertainty about outcomes and the huge impact of decisions during this phase for the overall development process. Thus activities at the start of product development generally show great variance and rely on interdisciplinary expertise across organizational boundaries.

For the purpose of our analysis we concentrate on *technological, operational* and *organizational* (firm-internal) determinants for our conceptual framework of successful product-process development transfer.[4] The new product development process has been described by sequential or overlapping phases from strategic planning and concept generation, pre-technical evaluation, technical development, and commercialization (Griffin and Hauser 1996; Veryzer 1998). Thus, development activities are regarded as entities which receive input information from preceding activities and convert it into output information for successive activities (Clark and Fujimoto 1991; Krishnan et al. 1997; Gerwin and Barrowman 2002).

[4] The literature uses various terms depending on the timing of the transfer from product to process development, i.e. overlap and/or interaction, information processing development, concurrent engineering, design for manufacturing, early manufacturing involvement, ramp-up.

2.1.1 Technological determinants

Technological determinants in the context of product development refer to two specific sets of technology: product and (manufacturing) process technology. These are, respectively, the technology used in the product and the technology used to manufacture the product (Tatikonda and Montoya-Weiss 2001); We differentiate technology-inherent characteristics and firm-inherent characteristics. Especially, factors influencing the product to process development transfer relate to technological complexity, product/prototype quality and technological familiarity. These factors are all closely related and sources of technological uncertainty/risk (Tatikonda and Rosenthal 2000b). Every new product development project is unique in terms of its technology novelty and complexity which also poses certain challenges for its execution (Griffin 1997; Tatikonda and Rosenthal 2000b). According to Griffin (1997), project complexity defines inherent characteristics of the project and hence influences the overall strategy of the project as well as its transferability. The project complexity is also somewhat related to the novelty of the technology/product but also depends on the size and scope of the project or the number of product functions embodied in the product, the number of components, and the number of parts. Lastly, the project also comprises higher complexity with increased time-to-market objectives and technology interdependence (Griffin 1997; Tatikonda and Rosenthal 2000a). Hence, Tatikonda and Rosenthal (2000a) define and measure complexity as "quantity, and magnitude of organizational subtasks and subtask interactions posed by the project" (p. 78).

The quality of the prototype can also influence the success of the transfer to a large-scale production process. A low product quality and functionality will cause additional iterations during production scale-up—where the prototype has to be reconfigured—which will lead to delays and transfer inefficiencies. Overall, the prototype quality will determine whether additional tests and feedback loops are needed. Uncertainty regarding the prototype efficacy can be reduced e.g. by asking customers to evaluate early prototypes in focus groups and testing the feasibility of alternative technical solutions early on (e.g. by probing functional prototypes under laboratory conditions). As a consequence, all development projects will have prototype issues that need to be detected and solved to avoid difficulties when transferring from product to process development (Terwiesch et al. 2001).

The novelty of the technology to be developed can be a major source of uncertainty in product development. Usually, technology newness describes the familiarity with the technology or the degree of difference in the technologies relative to the existing product portfolio by the company (Henderson and Clark 1990; Adler et al. 1995). The technological innovation literature typically classifies technological innovations into two distinct categories: 'radical' or 'incremental' (Ettlie et al. 1984; Dewar and Dutton 1986). Radical technologies pose a greater source of uncertainty as they are by definition novel and firms are usually less familiar with them. Hence, they are also more difficult to transfer into process development than incremental innovations (Tatikonda and Rosenthal 2000b).

Finally, also the technological requirements internal to the company can influence the product and process development. Does the company possess all the necessary knowhow to actually develop the technology? Product development processes appear to be particularly complicated when firms have limited experience with the product and process technologies they expect to apply in or with a product development project or they do not possess the required knowhow to effectively manage the given technology (Gupta and Wilemon 1990; Wheelwright and Clark 1992a). As a result, the use of new, unproven, unknown or 'risky'

technologies can lead to unanticipated and adverse transfer results and hence overall project outcomes (Tatikonda and Rosenthal 2000b).

2.1.2 *Operational determinants*

Typically, operations management literature takes an internal view focusing on the technical development part of the overall development effort (Adler 1995; Hauptman and Hirji 1996; Tatikonda and Montoya-Weiss 2001). Product development and manufacturing processes are very complex by definition due to several operational factors involved such as: supplies, procurement, technical equipment, forecast, delays, the need for special parts, and the human factor that is people who are engaged at all points in the process (Chopra and Sodhi 2004). The more variables there are, the greater the possibility of disruption to smooth operations and the transfer between product and process development. Hence, operational determinants refer to product development capabilities, operating choices and conditions of the future manufacturing site. Operational product development capabilities describe the management's role to set target levels for the final product (product quality, unit cost, and time-to-market) and allocate resources across these different goals given overall resource constraints and priorities (Tatikonda and Montoya-Weiss 2001). The resource allocation based on managerial decision making also influences the operating choices and conditions such as the technical equipment and machinery as well as the production capacity and access to the raw materials needed in the product and process development. A major slowdown in the manufacturing process can result from inefficient and late supply of input factors and raw material (Richardson 1993; Wang et al. 2010). Alternatively, a smooth supply operation and well-managed inventory (lean production) stimulate production as scheduled (Chopra and Sodhi 2004). A regular production schedule may be delayed or hampered if a manufacturing process involves complex machines to complete production, a temporary malfunction or a breakdown in an necessary equipment can affect the manufacturing process. Identifying means of improving efficiency of all working parts of production promotes a continual and more efficient operation (Herrmann and Chincholkar 2001). Lastly, the firm's absolute production capacity will impact the ability of the firm to scale-up the production process (Bohn and Terwiesch 1999; Krishnan and Ulrich 2001; Terwiesch et al. 2001). Effective capacity utilization determines the plant's performance during production scale-up (Bohn and Terwiesch 1999).

2.1.3 *Organizational determinants*

Organizational determinants can be differentiated in organizational process factors and organization-encompassing structural factors. "Organizational process factors are characteristics of the organizational process of project execution, that is, the way in which a development project is managed and carried out *during* the technical development stages" (Tatikonda and Montoya-Weiss 2001, p. 154). Operation management literature describes process concurrency, formality, and adaptability as crucial organizational process factors (Tatikonda and Montoya-Weiss 2001). Process concurrency refers to the extent of simultaneity in the design or R&D engineering and production engineering efforts (Rosenthal 1992; Wheelwright and Clark 1992b; Ettlie 1995). Process formality characterizes the existence of an overall organizational process and structure for the development project (Cooper and Kleinschmidt 1990; Rosenthal 1992). Process adaptability describes the flexibility during the development to meet unforeseen circumstances, and offers scope of discretion to the responsible project management team (Moorman and Miner 1998). All

three characteristics may ultimately influence the success of the transfer from product to process development. The organization's *structural* setting, in which NPD is embedded, shows great variability across firms (Brown and Eisenhardt 1995). A firm-specific organizational structure is important for the adaptation and initiation of innovation (Ettlie and Reza 1992). Firms need to have an explicit set of organizational capabilities to derive valuable processes and products. Hence, the result of successful process development is an organizational routine for product development. Previous research shows that more integrated organizational structures will have an important positive influence on development performance in general, and lead times in particular (Clark and Fujimoto 1991; Pisano 1994; Iansiti 1995). Achieving an optimal transfer between process and product development requires mutual understanding of the beginning of process development. An ill-defined starting point of product development bears the risk that functional tasks and objectives of process development do not match with the ideal organizational structure of the innovation process. Furthermore, organizational structure also implies the co-location and specialization of different departments involved in the product and process development transfer. A strong team and task specialization reduces overlap and opportunities for exchange at the interface. Hence, product and process transfer becomes more complex. In many firms, R&D laboratories or centers and production facilities are functionally as well as spatially disconnected (Gourevitch et al. 2000; Terwiesch et al. 2001). In some industries, e.g. the hard-disk drive and automotive industries, tasks can be physically separated from design to manufacturing across long distances (Terwiesch et al. 2001). But even if tasks are separated locally or regionally, this can already cause problems for efficient transfer from product to process development. In contrast, the proximity of R&D department and production facilities reduces coordination costs that are inherent to outsourcing manufacturing (van Mieghem 1999; Arnold 2000; McIvor 2009) as coordination and face-to-face communication among the decision makers involved in the transfer process is facilitated through more direct interaction and hence strengthened relational ties (Cummings and Teng 2003; Boschma 2005; Ganesan et al. 2005). Additionally, this functional integration is closely related to managerial systems and personnel factors which can closely monitor and control the process development (Leonard-Barton 1992). Nonetheless, functional differences can also be a source of conflict at the interface of product and process transfer due to differences in time horizons, different expectations, different underlying knowledge bases, insufficient communication, and infrequency of contact (Roussel et al. 1991). As a result, we propose a framework (see Fig. 1) accounting for the above mentioned technological, operational, and organizational determinants of product-process development transfer in biotech.

2.2 Uncertainty reduction theory

Innovation is inherently uncertain due to unforeseen risks related to product design, production and commercialization in vaguely defined markets. Internal sources of uncertainty in new product and process development go hand in hand with the three technological, operational and organizational determinants mentioned above. Thus, uncertainty in the innovation process has often been defined by technological uncertainty (e.g. engineering changes during the project as described in the previous section) (Loch and Terwiesch 1998; Koufteros et al. 2005) and other environmental uncertainties (Song and Montoya-Weiss 2001). Uncertainty resulting from operations refer to delays in supply of needed input factors, broken machinery/equipment or limited capacity. Furthermore, Song and Montoya-Weiss (2001) assert that uncertainty in NPD projects can also originate from other

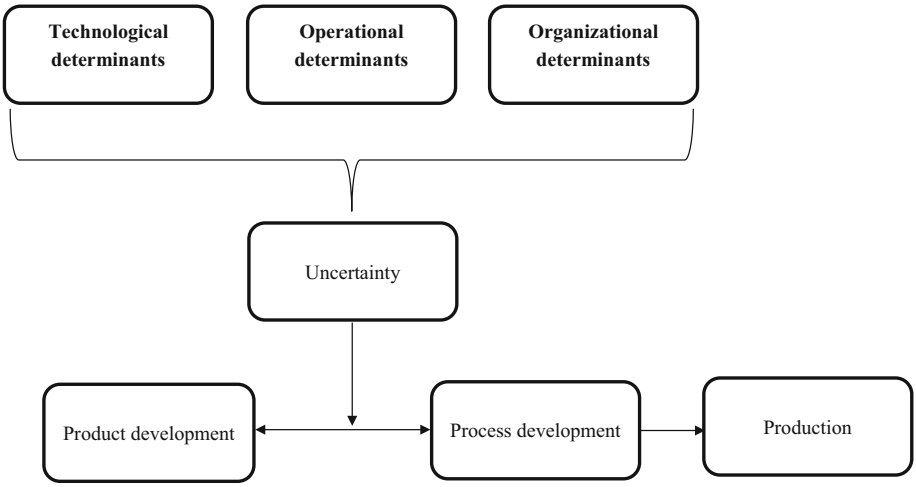

Fig. 1 Conceptual model

firm-level factors, such as organizational culture or structure which relates to the organizational determinants domain.

Particularly, during innovation processes—which are by definition risky or even uncertain—firms realize that they do not possess all necessary information for effectively managing change (Koufteros et al. 2002). Additionally, uncertainty usually leads to a greater specialization of functions and departments within organizations which in turn increases coordination efforts among those (Souder et al. 1998). One strategy firms apply to reduce uncertainty is to process more information or become more effective at it. Information processing requires project team members from different departments and specializations to share information and converge on a shared vision for the innovation project (Daft and Lengel 1986; Troy et al. 2008). When uncertainty during the innovation process increases an alternative strategy firms employ it to restructure their product development process to increase integration and knowledge exchange (Gupta et al. 1986; Koufteros et al. 2002). Hence, uncertainty reduction theory explains the perceived need for interconnected product development practices that help product and process development teams cope with the ambiguity of their task environment and, thereby, enact a shared team vision more quickly (Koufteros et al. 2005). As a result, teams are able to share critical information more effectively which further reduces uncertainty associated with the innovation process. Thus, high uncertainty during an innovation process creates a greater need to access and process more information and a greater integration among organizational departments, teams, etc. In contrast, a stable environment typically results in fewer, more foreseeable threats to the organization. When uncertainty is low, organizations can also effectively operate even when they are less integrated and more specialized (Souder et al. 1998; Troy et al. 2008).

Therefore, the main question based on uncertainty reduction theory is: How can firms manage and reduce uncertainty in the process from product to process development? Literature provides an ambiguous picture with regard to the question whether parallel or sequential product and process development reduces uncertainty better. The nature of product development and process development implies a sequential succession within the innovation process but several empirical studies have indicated that integrative, parallel

development activities can lead to superior outcomes (Clark and Fujimoto 1991; Eisenhardt and Tabrizi 1995; Terwiesch and Loch 1999). Efficient integration weighs the advantages against the disadvantages of sequential (e.g. waterfall model) versus parallel development. On the one hand, sequential development does not rely on iterations and projects are only transferred once a particular development step is completed. On the other hand, parallel development relies on iterations from the very beginning in order to address feasibility. Iterations usually reduce uncertainties with regard to the requirements of the complementary development units and avoid rework later on. Nevertheless, parallel development is not necessarily associated with optimal development as iterations are time-consuming and costly (Smith and Eppinger 1997). Under unfavorable conditions, parallel development can be more costly and last even longer than sequential development. On the basis of mathematical models, Krishnan et al. (1997) as well as Loch and Terwiesch (1998) show that more integration does not necessarily lead to superior outcomes. Dependent on contingencies such as task characteristics and the level of uncertainty different degrees of integration are ideal.

Based on the foregoing discussion, two questions arise: (1) Which mechanisms are useful to improve the product-to process development transfer? (2) How can coping mechanisms mitigate transfer uncertainty?

2.3 Standardization as a mechanism to overcome transfer uncertainty

The form of integrating mechanisms used in product to process development transfer varies widely across different organizations (Ettlie 1995). So far, considerable effort has gone into the examination of organizational techniques (e.g. employee rotation; personnel integration; cross-functional teams) for integrating development units and hence facilitating transfer (Liker et al. 1999). Cross-functional integration in an NPD project team refers to the magnitude of interaction and communication, the level of information sharing, the degree of coordination, and the extent of joint involvement across functions in specific NPD tasks (Clark and Fujimoto 1990, 1991; Wheelwright and Clark 1992b). The basic theoretical argument behind this reasoning is, due to a broader functional diversity, the amount and variety of information available to team members increases drastically. Hence, team members are more likely to understand the product development problem and potential solutions and are thus more likely to solve complex problems such as transferring a product from a prototype to large-scale production (Milliken and Martins 1996).

A complement to cross-functional integration is standardization. In the context of innovation, standards are most intuitively related to the compatibility of new products (Besen and Farrell 1994). However, standardization is much more versatile and has many different applications. Prior studies confirm that standardization facilitates the harmonization of terminologies, the coordination of measurement and testing procedures, as well as flawless data exchange at interfaces (Blind and Gauch 2009). So far, the following five types of standards have been identified in the literature (Blind and Gauch 2009): terminology standards, measurement and testing standards, interface standards, compatibility standards, and quality standards. In the following, we will present how these different types of standards can help overcome uncertainties regarding the technological, operational and organizational determinants influencing the transfer from product to process development.

2.3.1 *Overcoming uncertainties related to technological determinants*

In the innovation management literature, standards are discussed as integrative mechanisms that reduce the number of alternative solutions, through a process of selection, and through convergence on dominant designs (Gilsing and Nooteboom 2006). Standardization enables organizational learning across product generations (Leonard-Barton 1992; Ward et al. 1995) and hence decreases the likelihood to reinvent the wheel. Time and money saved due to standardization can then be used for creative problem solving and interpersonal exchanges that can focus on higher order issues (Liker et al. 1999). Furthermore, standardization strengthens a holistic design and consistent development framework for a series of products which eventually also has a positive impact on product quality but at the same time also imposes external constraints on the solution space (Liker et al. 1999). Standards help overcome the *technological* gap from product to process development as they facilitate the sharing of knowledge and coordination of R&D efforts (Delcamp and Leiponen 2014) and help to reduce problems related to technological novelty for example. Particularly, in cases of incremental innovation, standardized, comprehensive datasheets and processes help engineers to quickly determine whether the behavior of a device or prototype will meet the requirements of a large-scale system in which the device might be used (Liker et al. 1999). Moreover, product developers may use design standards to develop products based on highly compatible modules and subsystems that could be reused across models and generations (Lundquist et al. 1996). As a result, based on previous data, certain features of the new product or technology can be cross-validated using rigorous standardization (through established parameters) to reduce variation, improve product quality and measure performance of new, unfamiliar technologies. This creates both flexibility and predictable outcomes that are particularly useful when a prototype needs to be quickly scaled up to a serial production.

Regarding technology complexity, standardization may help to break down the technology and its production into several components to further reduce complexity. Moreover, the core knowhow related to each component can be modularized and hence simplified. As a result the components can be more easily reassembled as standardization is an ''activity (…) aimed at the achievement of the optimum degree of order in a given context'' (ISO/IEC 2004, p. 1). Additionally, standards may also be viewed as 'synchronized development tools' which affect all functional units of the innovation process. Hence, standards can act as knowledge exchange platforms for the different actors in product-process development that reduces complexity along the innovation process (Krishnan and Gupta 2001). Due to standardization firms are more likely to successfully transfer a complex product prototype to scale-up production. For complex technologies, such as nanotechnology, Leech and Scott (2017) introduce documentary standards as early-stage standards that are formulated via a consensus process covering a set of technical issues ranging across terminology, measurement, and labeling. They are set down early in the life cycle of the development of new technologies and are the predecessors of later-stage physical measurement standards in research and development efforts and the resulting commercialized products and services.

Due to standardized product characteristics and stage gates along the innovation process, product quality should be higher and hence when certain criteria are adhered to, the scale-up to large production should be facilitated. The necessary condition however is to have a good product quality already before scale up.

2.4 Overcoming uncertainties related to operational determinants

Overcoming uncertainty related to *operational* determinants, particularly quality standardization may be useful. Certifications such as ISO-9000/1 and regular (standardized) machine maintenance result in greater reliability and predictability of quality and technical equipment when scaling-up. Optimal production capacity needs to be analyzed with sensors or computer programs (digitalization of manufacturing processes can be helpful here). If a certain threshold is reached an implemented warning tool can send a signal before any problems arise. The company then either needs to increase its production facilities and capacities or outsource the production to third parties. A standardized course of action and planning can also be useful to deal with situations of access capacity. A well maintained production schedule is a prerequisite. Standardized, comprehensive datasheets and processes are widely used in many engineering disciplines (Canton et al. 2008). For example, supplier management and overview tools are frequently used by sophisticated purchase and procurement departments. These standardized documentation tools and databases send out warnings or flag risky suppliers that are potentially not going to deliver on time. Overall, a well-managed supply chain and inventory is a necessity to avoid any raw material shortage during the production scale-up (Chopra and Sodhi 2004).

2.5 Overcoming uncertainties related to organizational determinants

Finally, the *organizational* gap can be conquered by using standards to install routines, manuals and better integrated coordination mechanisms that have to be followed. Particularly, company standardization creates explicit and codified process knowhow that can be applied to transfer resulting knowledge from the lab to the plant and thus deal with the problems resulting from the organizational gap (particularly between scientists/researchers and process engineers) in product-process development. Additionally, standards may facilitate technology transfer by providing privileged access to interdisciplinary knowhow. As a result, we assume that standards are capable of providing a seamless transition from product development to process development. Großmann et al. (2016) show that standards can serve as knowledge and technology transfer mechanisms in new product development. Standards and routines embody codified knowledge repositories (Cowan 2000) providing structured information for optimal product-process integration. Additionally, quality standards can serve as reliable codified mechanisms to manage and control process development. Well-established standards for quality assurance and process control, production scheduling, changeovers, maintenance, and other production activities define clear constraints about the feasibility of different process technologies within an actual production environment (Pisano 1994).

Moreover, there are many different project management standards and certifications, such as Six Sigma and PMI's (Project Management Institute) Project Management Professional (PMP)® certification. These certifications standardize the organizational structure in terms of project management routines which are needed to develop and maintain a professional management system for product and process development.

Standardization can also be beneficial for process concurrency, adaptability and formality. With the help of standardization, a product to process development process can be broken down into many, well defined, discrete, measurable, and controllable steps where smaller changes and issues can be anticipated upfront, while preserving flexibility and resources for learning, to respond to surprises more quickly and when they occur

(Terwiesch et al. 2001). In short, standardization supports the design of an organized product development process that follows important formal criteria but at certain stages provides some degrees of freedom and concurrency when needed.

3 Methods

3.1 Research setting

The product development process in biotech can be broken down into distinct sequential stages (Giovannetti and Morrison 2000; Khilji et al. 2006, pp. 46–47). Product development in biotech starts with the discovery and synthesis of a molecule assumed to have desirable therapeutic effects. After sequentially testing for safety, efficacy, and proper dosage strength and form the compound may develop into a drug (Kaitin 2010). First, the compound is tested on laboratory animals to determine if it has any toxic adverse reactions. Second, if it meets this first threshold, to further ascertain safety, the drug is then tested on human patients (Phase I trials). Next, its efficacy at different dosage strengths (Phase II trials), and its overall efficacy (compared with existing treatments or a placebo) in a large patient sample (Phase III trials) are examined (FDA). Finally, data obtained from these clinical trials are then sent to regulatory bodies (e.g., the Food and Drug Administration—FDA-in the US or the European Medicines Agency—EMA in Europe) for inspection (Giovannetti and Morrison 2000; Rothaermel and Deeds 2004). After formal approval by the FDA (or its equivalent outside the USA) the drug can then be sold commercially (Bianchi et al. 2011). The overall time frame of drug development from compound discovery until approval for sale can take anywhere from 3 to 12 years (see Fig. 2 for an overview of the phases of product development in biotech).[5]

Process development is the result of learning and experimentation. Initially, molecular biologists produce a newly discovered or synthesized molecule in very small quantities at very high cost which do not compare to any commercially viable production processes (Takors 2012). Specifically, a commercial process does not only manufacture the compound in much larger quantities (metric tons vs. grams), it also has to extract it in extremely pure form, at reasonable costs, and within regulatory restrictions (Rathore 2016). Hence, processes pass three (often iterative) development stages: process research, pilot development, and commercial plant scale-up (Hall and Bagchi-Sen 2002). Firms have resources available that they can allocate across these three phases. Process research involves defining the basic structure of the process. For biotechnological processes this stage typically defines the basic architecture of the process, rather than all the details e.g. deciding which type of cell (bacterial or mammalian) will be used to produce the protein (Pisano 1991). This is closely related to the 'concept development' phase in most product development activities. Thus, firms often end up with several different theoretical routes to synthesize the desired molecule (Pisano 1994). Based on these thought experiments they run small-scale experiments in laboratory settings to generate important data and validate knowledge (Takors 2012). In a typical setting the molecular biologist knows a particular platform to generate substances on a small scale. It may be inefficient and not scalable but

[5] The odds of a discovered molecule succeeding in the development process are extremely low (0.01%). For every 10,000 compounds screened, 250 (2.5%) so-called lead candidates make it into preclinical testing. Out of those lead candidates, five (2%) enter clinical testing, 80% pass phase I, 30 percent pass phase 2, and 80% pass phase 3 of the clinical trial (Rothaermel and Deeds 2004).

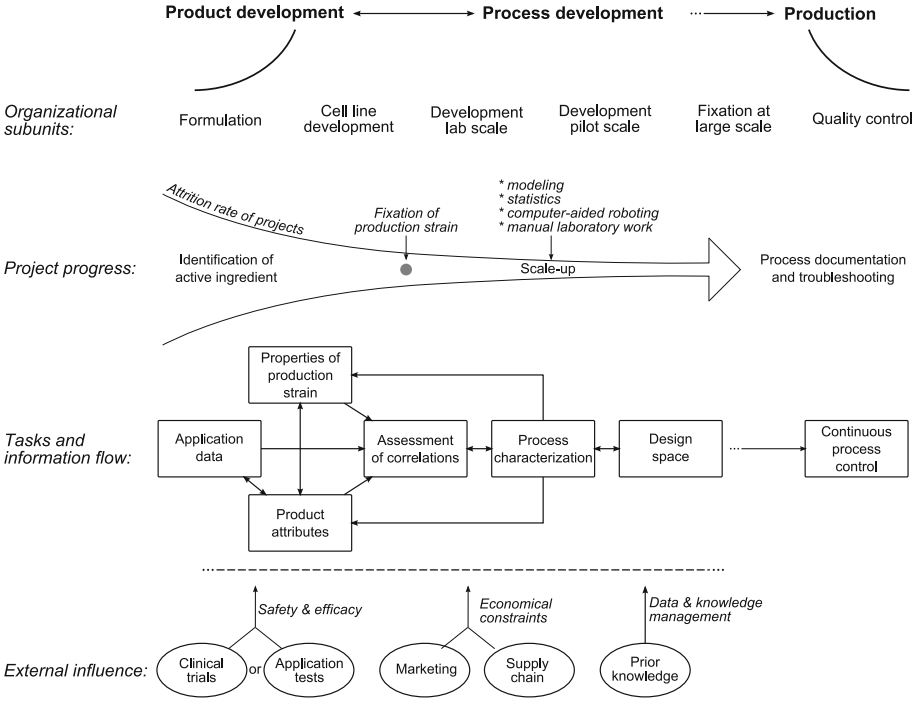

Fig. 2 Overview of the front end of process development in the biotechnology industry (own figure; developed based on previous literature)

for the researcher showing efficacy is more important. Pilot development involves optimizing the efficiency of the process by refining and scaling it up. In many companies, process development is organized in different departments and thus conducted by people with different backgrounds (e.g., biochemical engineers vs. biologists). Finally, commercial start-up involves the transfer and adaptation of the process to a factory to produce the drug on a large commercial scale (Pisano 1994). Often, during the transfer unexpected problems arise due to clashes of process R&D with the realities of the factory. Firms can better prepare for any occurring problems by integrating knowledge about the factory environment during research and pilot development. Once the plant can produce a fixed amount of drugs which meet the quality standards the transfer process is complete (Pisano 1996). In sum, product development in biotechnology consists of two interfaces: one interface between the research and process development, and another one between the process development and production.[6] This paper focuses on the first interface.

3.2 Data collection

Given the complexity of the front end in biotech as well as the exploratory nature of this study, we use a multiple holistic case study design as we include one or two key informants on one level for each of our different case organizations (Yin 1984; Giovannetti and

[6] In contrast, pharma companies are typically organized in R&D—which contains product and cell line development—and manufacturing which contains process development and operations. These two departments often operate in silos.

Morrison 2000; Eisenhardt and Graebner 2007). Moreover, we conduct a comparative case study using several experts at different biotech institutions to compare these cases among each other. The cases are evaluated based on qualitative methods which allows for a combination of theory building and theory testing (Creswell 2002; Tashakkori and Teddlie 2002).

Triangulation of evidence and validity of the results is supported by different data sources (Yin 1984). From December 2011 till October 2012 we conducted 31 in-depth interviews in 21 different institutions in the biotechnology industry. This means that some of the respondents are affiliated with the same institution. The experts are either affiliated with institutions in medical biotechnology, industrial biotechnology or both. Their respective positions range from tenured professors, CTOs, CSOs, CEOs, group leaders, project leaders or principal scientists. On average an interview took 1 h and 17 min. Each semi-structured interview was prepared by an extensive web search. The interviews were electronically recorded, accompanied by personal notes, and transcribed. Confidentiality was guaranteed to all interviewees. Additional secondary data such as regulatory guidance and best practice reports were accumulated along the research project. Please see Table 1 for an overview of the interviewees.

Following the techniques of grounded theory, professionals were chosen with the objective to achieve a maximum level of information and individuals were added to the sample until theoretical saturation was reached (Glaser and Strauss 1967). Potential interviewees were approached under the title 'Interface between product and process development'. Interviews were conducted in a cooperative and open-minded environment and were always conducted by the same researcher.

The semi-structured interviews were based on an interview guide divided into five sections. The first two sections were concerned with personal data and the general set-up of the interviewed institution, respectively. While the third section addressed issues of process development as a whole, the fourth and most extensive section questions the interaction between product and process development. At the end, the fifth section investigated a case example for the last transfer between product and process development which the interviewee had experienced. The semi-structured interview guide mainly consisted of open ended questions. Before starting the data collection, the interview guide was pre-tested with experts and revised. At the beginning of each interview, all participants were asked to give concrete examples and explanations from their personal work environment to create a mindset that reflects reality as close as possible.

3.3 Sample description

Since we conduct confirmatory case study research our sampling procedure was theory-driven. The context for our analysis is based on the biotechnology sector. Biotech is characterized by a huge number of small firms that are organized similar to university laboratories where scientists often work autonomously on their own projects. Innovation is critical for firms' long-term survival. Biotechnology firms face heavy upfront investments in R&D (Hall and Bagchi-Sen 2002). In the past, the biotechnology industry struggled to capitalize on outstanding ideas and bringing scientific breakthroughs to market. One explanation is that the NPD process in biotechnology is exceptionally time consuming, costly and complex (Azoulay et al. 2010; Pisano 2010) as there are many different players involved and there is no guarantee of commercial success (Hall and Bagchi-Sen 2002). For instance, development times are much longer than in other high-technology industries: 2 to 3 years in industrial biotechnology and up to 15 years in medical biotechnology

Table 1 Overview of the interview partners

Nr.	Position	Duration	Affiliation (Years)	Educational background	Industry branch
1	CSO/CTO	1 h, 36 min	19	Biochemistry	Industrial biotechnology
2	CEO	40 min	4	General engineering	Industrial biotechnology
3	Project Leader	1 h, 39 min	2	Microbiology	Industrial biotechnology
4	CEO	55 min	8	Biotechnology	Industrial biotechnology
6	Principle Scientist	50 min	11	Biochemistry	Industrial biotechnology
8	Project Leader	1 h, 32 min	15	Chemical engineering	Industrial biotechnology
9	Project Leader	1 h, 15 min	7	Biotechnology	Industrial biotechnology
10	Group Leader	1 h, 23 min	5	Chemistry	Industrial biotechnology
11	CEO	2 h, 25 min	3	Chemistry	Industrial biotechnology
18	Project Leader	47 min	3	Chemical engineering	Industrial biotechnology
19	Project Leader	1 h, 8 min	19	Microbiology	Industrial biotechnology
27	Group Leader	1 h, 14 min	4	Chemical engineering	Industrial biotechnology
28	Professor (with tenure)	1 h, 16 min	10	Chemistry	Industrial biotechnology
31	Professor (with tenure)	58 min	13	Chemistry	Industrial biotechnology
5	Group Leader	1 h, 23 min	6	Biotechnology	Medical biotechnology
13	Project Leader	58 min	4	Biotechnology	Medical biotechnology
14	Project Leader	1 h, 4 min	2	Biotechnology	Medical biotechnology
15	Group Leader	1 h, 39 min	6	Biotechnology	Medical biotechnology
16	Group Leader	1 h, 59 min	12	Microbiology	Medical biotechnology
17	Professor (with tenure)	1 h, 4 min	12	Chemical engineering	Medical biotechnology
20	Project Leader	1 h, 54 min	4	Biotechnology	Medical biotechnology
23	CSO	47 min	15	Biochemistry	Medical biotechnology
24	Project Leader	1 h, 48 min	12	Chemistry	Medical biotechnology
25	Group Leader	1 h, 10 min	13	Microbiology	Medical biotechnology
26	Group Leader	1 h, 58 min	6	Microbiology	Medical biotechnology
30	Professor (with tenure)	1 h, 7 min	4	General engineering	Medical biotechnology
7	Principle Scientist	1 h, 18 min	5	Biotechnology	Industrial & medical biotechnology
12	CEO	32 min	10	Chemistry	Industrial & medical biotechnology
21	CTO	1 h, 27 min	5	Biotechnology	Industrial & medical biotechnology
22	CSO	1 h, 25 min	6	Biotechnology	Industrial & medical biotechnology
29	Professor (with tenure)	48 min	4	Microbiology	Industrial & medical biotechnology

(Jungbauer and Göbel 2012). In comparison, the development time in the electronic industry takes on average 17.4 months (Zirger and Hartley 1996). Furthermore, the NPD process in biotechnology displays the characteristics of open innovation (Chesbrough 2003; Bianchi et al. 2011). This means:

- Technology transfers across organizational boundaries take place and special services are outsourced to contract research organizations.
- Biotech firms intensively collaborate with other partners, e.g. large pharmaceutical firms. Complex tasks and interdisciplinary work teams promote the creation of worldwide networks (Powell et al. 1996).

These industry characteristics emphasize the need for models and procedures of efficient transfer from invention to production in biotechnology. However, the characteristics of biotechnology can also be found in other industries such as nanotechnology (Robinson et al. 2007). Therefore, solutions and findings might be transferred and provide evidence for general patterns.

The sample differentiates between experts from industrial and medical biotechnology, which are the two most important branches in biotechnology. Product and process developers from different hierarchical levels are contained in the sample to avoid a one-sided perspective. Furthermore, based on the years of affiliation respondents are sufficiently familiar with their organization to provide detailed information about the specific NPD process in their firm. Noteworthy is the broad heterogeneity of the interviewees with regard to their educational background. This already indicates that in biotechnology very different disciplines need to be combined within and across functional units. Different educational backgrounds can lead to different mindsets and perspectives towards the perception of problems which eventually plays an important role for the interface between product and process development. The sample is also diverse with regard to the size of the employer. The smallest company consists of 3 employees, while the largest company employs more than 100,000 employees. In total, 12 cases were investigated in large companies and 14 cases in small-and-medium-sized companies. Academia often plays a crucial role for NPD in biotechnology. Hence, 5 in-depth interviews were conducted with biotechnology professors which had extensive experience with industry cooperation in the past.

3.4 Data analysis

The data analysis combines inductive and deductive reasoning. The conjunction of the two can also be described as retroductive approach (Downward and Mearman 2007). Every in-depth interview was transcribed immediately after each meeting. We used the qualitative data software Atlas.ti 7 to analyze the interviews.

Based on the literature review, a basic structure of main codes was established and agreed among the researchers. The coding work was done by two different people to ensure objectivity. The primary coding scheme was then extended or verified while coding the first interviews in order to guarantee a high compliance with reality (Strauss and Corbin 1994). Thus, the initial coding scheme was iteratively refined along the analysis. We grouped codes to categories and then further abstracted them to concepts in a stepwise approach (see Online Appendix). Therefore, all results are illustrated by considerable quotes from the practitioners (Azoulay et al. 2010). Actual quotes in combination with the predefined approach to data collection, coding and theory building ensure objectivity and validity of the results.

4 Results

This paper examines the development of production processes in general and applies it to biochemical[7] compounds, in particular. In accordance with the theoretical background presented in Sect. 2, the results of our analyses are organized along these three subcategories. We first provide an overview of the three influencing (technological, operational, organizational) determinants at the beginning of process development. Secondly, important uncertainties in the product-process development are presented. Finally, the role of standardization and its effect on the product-process transfer is assessed.

4.1 Boundary conditions of product-process development transfer

An in-depth investigation of the beginning of process development reveals the convoluted nature of the interface with R&D. In addition to the firm-internal determinants (of technological, operational, organizational determinants) based on previous literature, key informants have identified additional determinants (relational and market determinants) affecting the transfer between product and process development.

4.1.1 Technological determinants

The main challenge in early process development in biotechnology is the definition of technical product characteristics and quality attributes particularly accounting for the feasibility of large-scale plant production. When this approach is consistently implemented up until manufacturing or large-scale production, it is accurately described by 'planning with the end in mind' (Yu 2008). The prospective manufacturing process interacts during the development phase through its impact on the product attributes directly and the properties of the production strain indirectly.

Technological complexity

There is no consensus about the impact of technological complexity. Some interviewees state that complexity can usually be overcome with more iterations and hence higher costs, others state that this is an important driver of effective transfer and hence success. Often, the interviewees argue that complexity—which depends on the organism or product—prevents or limits scale-up. Simple products can also be more easily transferred.

> […] you have to reduce the technical complexity as effectively as possible. The higher the complexity, the more challenging is the process transfer. (Interviewee 25)

> The more technical complex issues we have been bringing into our process development the more difficult it's been to complete the process. And so I find that this is a huge issue to its success. Specifically, they granuloma project. We want to go this route but we had many technical problems that have been brought up that we cannot solve yet. Instead of working 24/7 on this project we have basically shelved it. It has been spending more money rather than creating money. (Interviewee 3)

[7] 'Biochemicals' is used to describe large protein molecules produced from genetically engineered cells (biotechnology). Hence, we do not focus on pharmaceutical production processes as these are fundamentally different from biotech development processes.

The respondents state that almost all technical problems can be solved as long as there is communication and feedback from the front and back-end to clearly define what the process department needs to start and whether it is developing in the right direction. Sometimes experimentation—often related to time and resources—can solve technical problems.

Product quality

First, an indicator for successful transfer from product to process development is a high product yield with consistent quality or improved quality. Second, successful process development goes back to having a product relatively quickly and without major changes between laboratory, pilot and industrial scale. Third, another success criterion is that this process can be sustained in production, that it is robust enough and that the product quality is not influenced by slight variability in the process or production process.

> The overall goal was to have a product that is similar in quality and safety and potency as the original molecule. That was the big target. (Interviewee 17)

> The quality, that can be the purity, but it can also be the consistency. So whether the pellet is a bit more solid or whether it is rather squishy. These are things that can have a very decisive influence on whether the process you have devised on a small scale is still applicable. (Interviewee 26)

Technological novelty/dynamism

Biotechnology is a fast moving industry with new tools, methods, and applications evolving on a yearly basis, e.g. CRISPR-CAS, CAR-T cells, micro RNA. Previous biotech generations were mainly concerned with fermentation and organic chemistry. The third generation now incorporates biological engineering and life sciences and has many more commercial applications (e.g. in agriculture and environment) due to recent progress in biology research (McKelvey et al. 2004). Moreover, it is a very dynamic industry that requires fast decision making and development cycles to gain lead time advantage and enter the market first (Madhok and Osegowitsch 2000). Additionally, biotech as an industry is fast growing, many firms are founded, others merge, relocate, spin-off new ventures or go out of business (Zhang and Patel 2005).

> Then it's primarily about time. Namely, the time to gain market share over my competitors by simply being faster in the next clinical phase, so that I go to market faster. And it can sometimes be weeks that really matter. If any competitor is going into a niche indication that we're targeting, for example. (Interviewee 15)

Additionally, technology and product newness are seen as a limiting factor as (radically) new compounds usually require a new process as well where economies of scope or learning effects cannot be further exploited.

> Maybe that's simplistic but in the end of the day I think regardless of how the processes are done we would still be able to make more products that are beneficial but if we are just trying to create a new process every time we have a new product that is just going to create difficulty. I think even though humans are very intelligent consistency and simplicity is always better. (Interviewee 3)

Additionally, feasibility in the transfer of a product idea to a large-scale process can be another problematic factor. Some ideas will simply not work or easily transfer to large-scale production.

> Scientists they like process development because it's about new ideas. But they get frustrated if their new ideas don't get implemented because they don't understand the process. So they might come up with some wild new additive that you just cannot afford but they don't have an economic model that tells them this is not affordable. So they might work for years trying to develop something and then it can't be implemented. (Interviewee 19)

Familiarity and hence technological novelty also plays an important role in biotech process development. Familiarity usually associates with the experience of the developers involved.

> That always depends on the assignment. There are a few areas where we already have experience with similar substances or even in the same areas and this is a relatively safe thing. There are also areas, where it also depends a bit on the literature that we have, then of course it is more difficult, then it is not sure if it works. Then you have to define certain termination criteria that you say okay, if it doesn't work, then don't do it. (Interviewee 26)

> It simply takes, needs an enormous experience to understand a bioprocess. If you have a very competent person, whom nobody can fool, because he has already gone through 100 processes. If he gets data and he gets good data, he will rely on it. (Interviewee 29)

4.1.2 Operational determinants

Tasks and objectives at the front end of process development are manifold and substantially change as process development matures. At the interface between product development and process development the two units jointly have to determine the production cell line or strain that is able to express the protein of interest.

Technical equipment

Access to technical equipment could be a limiting factor when it comes to product and process development in biotech. The interviewees have opposing views on this also depending on the different organizations they work for. Usually, smaller companies and universities face more problems regarding access to technical equipment than large, established companies.

> No, because the strategy of the company is never to do all the research by ourselves. So I don't think that (technical equipment) is a limitation for us. When we have this issue (of not having the right technical equipment) we would make an agreement with the partner or we would buy the proper instrument. (Interviewee 3)

> Missing technical equipment is a limiting factor. Sure, otherwise we couldn't do our good research. We already have great equipment. But if it were even better, it would work even better. (Interviewee 23)

> Yes, you can still wish for a few more sophisticated devices. I don't think there's anyone who wouldn't say he couldn't use this or that. Of course, there's always a limitation that you can't have everything. (Interviewee 4)

Capacity

Production capacity can be a barrier particularly when a company tries to scale up its production. If the companies—however—realize that they reach capacity limit, they usually collaborate with contract companies that offer their production facilities for larger scale development.

> So it's mostly done in-house. But there is a certain percentage, however, which is definitely given out to contract developers. But that is a rather small percentage. People are trying to do this in-house first. It is only released if the capacities are not sufficient. This is looked at several times a year and it is decided whether to develop a certain process in-house or not. (Interviewee 20)

> Or let's say we filtered out a substance in the process that you love. Then you have to produce this substance naturally in grams or kilograms. We don't do that anymore. In other words, this will also be outsourced to companies that in principle offer this service. Internally, we produce up to one gram and externally everything that is larger than 1 g. This then exceeds the internal capacities. (Interviewee 23)

Supply

Only very few interviewees mention problems with suppliers but they acknowledge that this can overall delay the product to process development process as supplied material is usually tailored and specialized.

> Yes. That is the really significant problem that I run into. Custom-made probes for example for particular measurements. Finding companies that will make custom sensors has been a difficulty. Once we find a company, and it's typically small companies that will do the custom sensors and once they agree to do it, it takes half a year for them to do it because it's not off the shelf. (Interviewee 18)

Time

Another operational factor mentioned by the testimonials is time. Due to commercial pressure processes need to be developed as fast as possible. At the same time, they also have to be robust to not jeopardize the quality of the product (and potentially the health of a patient). Respondent emphasize that the aspired product quality determines the optimal production time. They do not want to sacrifice product quality for a very short process. In sum, time is often mentioned as a compromise for costs and quality.

> The other topic is the development times. Now there is a strong pressure on the development times so that the developer hardly has the chance to develop the process at all. It is more a portfolio management, a pushing through the processes from the early research to the production. I cannot be fast and collect lots of data at the same time. These are just two goals that run contrary. (Interviewee 15)

Resources/costs

Respondents additionally mention aspects related to financial resources. It is really important that a development project meets the projected costs. Therefore, costs need to be in a certain frame which is given by the customer. Additionally, development costs are heavily dependent on the resource endowment of the biotech firm. Resources are naturally more limited in small and start-up companies whereas large pharma companies usually do not face this constraint. Some organizations are particularly struggling with financial endowment and hence do not possess the best or latest technical equipment. Others face severe lack of qualified personnel. On the other hand, some interviewees state that product quality is more important than cost efficiency.

> Cost was never an issue. The issue was to have it rapid and of good quality. (Interviewee 17)

> Yes we are restricted by budgets. We don't have the products with such high margins that you can afford not thinking about the budget. (Interviewee 7)

4.1.3 Organizational determinants

Previous research shows that organizational structure, routines as well as other organization-inherent determinants will have an important influence on product-process transfer and development performance.

Firm culture and communication

Another frequently mentioned influencing factor is firm culture. Participants argue that an open culture facilitates not only communication between scientists and engineers it eventually also facilitates the transfer between product and process development.

> A very positive work experience is going to allow the transition to flow much more easily. (Interviewee 3)

Continuous, iterative communication between the units involved, e.g. research and development and production or marketing, is indispensable. Nevertheless, the respondents highlight that most of the time the scientists and developers do not speak the same language or do not use the same terms. After all, the involvement of people from different disciplines is important to actually accomplish the transfer between product and process development. Therefore, regular personal exchanges, visits to production, openness, clear communication and transparency at every stage of the process are key to success. Roles and responsibilities must be established and written down. This also entails a clear definition of the roles, who is responsible for what and from where to where.

> A steady flow of information. The transfer of important information. So filtering the information. Good cooperation. That all information really flow. That nobody holds back information. It is important to provide both the production and the development with important information. It cannot stop anywhere. If this is the case, there is a high probability that the project will be successful. (Interviewee 14)

Geographical distance

It is difficult to transfer complex product technologies into processes if they are not only spatially dislocated but if there are language, time zone, cultural and technical barriers on top preventing an efficient exchange. Therefore, regular personal or even virtual meetings are heavily encouraged by the interviewees. Nonetheless, the respondents also acknowledge that it does not matter whether the other entity is spatially 500 yards or 5000 miles apart, the problems remain. They also emphasize that the transfer is not further enabled by latest communication technologies but it becomes more complicated and less efficient instead.

> Although we were in the same facility they were in different buildings. That was a problem. Even within the same plant because people were working in another lab etc. That increases a little bit the difficulty of the interaction. (Interviewee 17)

Structure of organizational units

> Of course you have to have some kind of organizational structure and there have to be milestones and there have to be boundary transitions. Of course, these organizational boundaries lead to the loss of knowledge from one organization (or department) to another. (Interviewee 20)

The organizational structure of the front end as indicated by the allocation of the organizational subunits shows great variance across firms. Hence, depending on the firm, the internal organizational structure is organized differently or focuses on another subunit. In total, six organizational subunits (Formulation, Cell line development, Lab scale development, Pilot scale development, Large scale development, Quality control) are identified which represent a typical organizational structure in biotech product-process development. These subunits can be further divided or combined depending on the firm characteristics.

> I know different organizational forms. I know the production is responsible for something and development is responsible for something and both come together in case of a transfer, they identify appropriate responsibilities and then transfer this process. The other model I know there is a separate unit that performs the transfer. (Interviewee 15)

Additionally, the input for each of the different subunits may come from either product scientists or process engineers. For example, defining product quality attributes as well as screening for production strains requires many input variables from the product as well as from the process side. The interviews further reveal that these two subunits are assigned to either product development branches or process development branches—often due to historical reasons. A similar pattern can be observed with regard to the end of process development. Process control and process troubleshooting are assigned to either process development branches or production branches. Hence, path dependent behaviors determine which side of the interface deals with which subunit and an overall guiding principle cannot be derived as this is firm-specific.

> Since we do not have such a very strict and crystal clear separation between the process developers and the researchers, […], which then also blurrs the boundaries somehow, we then have fewer problems of handing over. (Interviewee 1)

> Yes but there are no boundaries whatsoever in our department. And then we have experts so some people are more scientific if you like and some people closer to production. But they are no separate communities. It's a grayscale. (Interviewee 7)

4.1.4 Relational determinants

Not only organizational boundaries but also characteristics of the personnel can cause a distance which increases uncertainty for the mode of the integration. Personal differences can be decisive factors for coordination mechanisms. Close, personal contact is undoubtedly mentioned as one major predicament for successful transfer. This is again closely related to trust building between the different entities involved. Both product and process developers need to trust in each other's capabilities, that everybody is working in the same direction and in the best interest of the firm.

> You need close interactions. Also on the personal level. And just to make sure there are no different agendas. (Interviewee 7)

Early stages of research and development in biotechnology are mostly performed by natural scientists. As the development project progresses, the focus is shifted to engineering personnel. Different educational backgrounds are based on dissimilar schools of thought and mindsets which eventually lead to diverse perceptions and evaluations of problems. In addition, along the scale-up of the volume, the size of the machinery increases and more workers are required to operate the machines. Thereby, the ratio of highly educated academics decreases. The nature of work at later development stages is increasingly coined by a mindset of compliance instead of creative problem identification and solution finding.

The described discrepancy results in two substantial uncertainties for project management. Firstly, complexity and effort at the 'other side' are difficult to estimate. This can lead to problems with regard to time lines or budget planning. Besides, detailed process understanding is possibly not generated to the extent which a holistic risk management plan would require. Secondly, commitment to coordination mechanisms on an emotional level is decreased through large sociocultural distance due to low appreciation and resentments towards the 'other side'. Furthermore, coordination mechanisms are typically not enforced through end-2-end incentive systems.

4.1.5 Market determinants

Product attributes must be aligned with application requirements which result from clinical trials or application tests and determine safety and efficacy data. These external influences are not only important in the beginning but also impact quality assurance in later stages, e.g. documentation during process control. Furthermore, marketing and supply chain influence the beginning of process development by setting production or economic constraints and limiting the set of acceptable process outcomes. Prior knowledge e.g. from customers becomes particularly important in series of project developments. Hence, customer specifications can be incorporated and might eventually influence the whole process. At an early stage the researcher already has to know how to produce, at what scales, which raw material to use, and which amounts to obtain.

> The earlier I take the market reality into account, the more likely I will be successful, or the more the success probability is given, that I will come thus far. This is just the corset in which we all have to move. What does the market or the consumer dictate? (Interviewee 22)

Additionally, regulatory forces play an important role as only once the FDA or EMA approve a new compound, large-scale manufacturing and commercialization commence.

> [A] limiting [factor] is to present the data how the authorities want to see them, how clinical testing institutes want to have them. (Interviewee 15)

Competition also is a relevant influencing external factor.

> The keyword is creativity. Here, we are not in the arts, but afterwards in a tough competition and you do not need to develop a process that ends up in the drawer, because then the creativity that goes into this is also worthless. (Interviewee 27)

In summary, the influencing factors of integration between product development and process development presented reveal that an isolated treatment of product development and process development does not align with reality. Additionally, we identified relational and market determinants as two additional dimensions with an impact on product and process development in biotechnology.

4.2 Uncertainty in process integration

The respondents acknowledge and mention several uncertainties in the product-process development that affect the transfer. Particularly, respondents express heterogeneous perceptions regarding time and content of optimal integration. This underlines the relevance of our research question, especially since biotech firms have become aware of integration as a decisive parameter for project success.

Moreover, sequential and parallel development seem to describe two extremes of a single continuum. Whether firms engage in sequential or parallel (integrated) product-process development is due to two underlying types of uncertainty:

1. Dependencies between product and process development
2. Project attrition rates

4.2.1 Dependencies between product and process development

Biotechnology as a field is relatively young. Since the protein molecules produced by biotechnology processes have complex structures, it can be very difficult to comprehend how a small change in the process might modify the structure of the protein. Only after years of experience a molecular biologist may be able to develop a heuristic to predict future performance from laboratory experiments (Pisano 1996). As a result, running lab experiments results in a higher number of iterations required to converge to the desired performance level eventually causing greater development cost. In contrast to the chemical industry process developers in biotechnology can only rely on little theory to search for and probe alternatives they also have limited practical experience due to the complexity of the subject matter. The weaker knowledge base underlying biotechnology production makes laboratory experiments very likely to be noisy. As a result, there is scarce research on the problems linked to designing and implementing large-scale biotechnology processes. In contrast, based on a rich base of theoretical and practical knowledge, engineering chemical processes provides better conditions to bring together, integrate, and generate the relevant knowledge, characterize the process and make predictions about process performance in laboratory settings. Additionally, it remains unclear whether the transfer from product to process development in biotechnology is sequential or overlapping.

> It's sequential. But in the transition we are parallel for a time. (Interviewee 14)

> It is more integrated, since through the process the product will be fine-tuned and manufactured. In this sense, this means that process development is at the same time a product development. (Interviewee 4)

The quotes show that there are different opinions about the benefits and disadvantages of sequential or parallel development. Additionally, if process development reveals problems several iterations might return the compound to the product development stage which render the transition "nested". Also, some of the interviewees maintain that a clear-cut transition is difficult and that it is hard to disentangle pre-defined transition stages.

> And if you notice it does not work with the product, you might start with the process. But it is nested. I will not say it is sequential, it is not parallel, but it is slightly nested. (Interviewee 28)

> I would always see sequential and parallel development as two bookend approach and 99% of companies do something in between, but at very different levels and degrees, and no one will really say one person is doing all the steps sequentially and no one will say I start all the steps at the same time. … So there's always something between these extremes. And the question is always to what degree do I do it. And the advantage of parallelization is that I can probably make it faster. Another advantage is that I am better, more interactive at the interfaces because the overlap is greater. And the big disadvantage is that I'm potentially developing things in vain, because I'm developing a formulation for a molecule, for example, where I find out that hey, this doesn't work the way I thought it would. Then I may have spent more money than necessary.
> On the other hand, there are people who follow the strategy "Fail fast, fail cheap". Full speed ahead, I'm just trying to show efficacy, so the product (my molecule) is working, everything else after that I don't care, if I have to redevelop and if it takes longer. The most important thing is, I know as quickly as possible if it works or not, and there are other people who say, no, we have to do more of that in parallel. Because then we save a lot of time and money. (Interviewee 26)

Additionally, the participants frequently mention technological complexity, path dependency, customer requirements and satisfaction, researchers' relevant experience and understanding of the interface, process development as intermediary between research and production, and limited financial and human resources as factors further augmenting uncertainty at this already complicated interface. Hence, higher uncertainties in the interplay of product and process development promote an earlier involvement of the downstream activities, i.e. process development. Potential benefits are fewer subsequent improvements in later stages and early feasibility tests. In more detail, the development stage at which the main responsibility of a project is transferred should also be chosen according to the degree of uncertainty which results from the interplay between the two units.

> The [transition] is actually very important because it should start very early and often starts much too late. Many products have not been produced since the process was no longer adaptable to the product. And no one wanted to invest more time and money to start over again. That is why this point in the transition from pure product

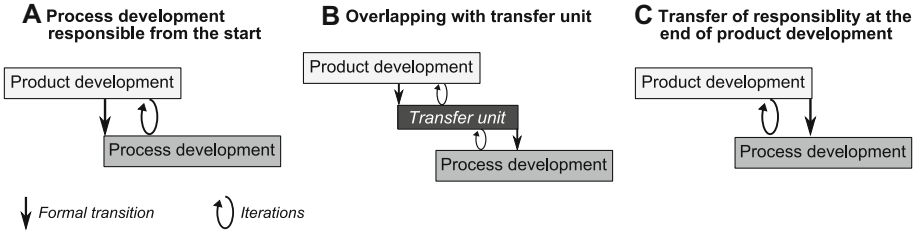

Fig. 3 Organizational structures of sequential/parallel development

development to process development, I regard it as crucial to the success of product development. (Interviewee 27)

This has an immediate effect on the relevance and complexity of the interface. The range of organizational structures handing over development projects accounting for iterations is illustrated in Fig. 3. If uncertainty with regard to downstream activities is high, formal project responsibility is transferred to the organizational unit of process development at an early stage (Fig. 3a). For example, the definition of quality attributes is assigned to process development. In this case, the required input from product development is still at a rudimentary level and the transfer is not perceived as particular challenging. In return, this increases the required resources as process development has to provide development capacities for a longer time.

If, in contrast, uncertainty is low, project responsibility is not transferred until optimal cell lines are determined. This case results in a complex project transfer (Fig. 3c) due to accumulated knowledge which has been gathered during the definition of quality attributes and cell screening. The main advantage of Fig. 3c is that in a critical development stage most of the activities come from only one source, but the extent of required content at the actual transfer is substantially increased.

In comparison, the two alternatives resemble a trade-off between handing over the responsibility too early or too late respectively. A hybrid model is presented in Fig. 3b where a separate unit specializes in the gray area between product and process development. The main objective for this unit is to design an ecosystem where information flow between two critical steps is facilitated. This structure comes only into consideration when transfers between product and process development reach a particular frequency.

Uncertainties due to the dependencies between product and process development can also be derived from the concept of path dependency. Path dependency explains the phenomenon that small differences in early development stages have unequally large impact on development outcomes (Anderson and Joglekar 2005). An illustrative example in biotechnology is the choice of the production strain which often results in lock-in situations for further development steps. A subsequent change of the production strain is usually very time-consuming, expensive and difficult at later stages.

Let's put it this way: We [process developers] have to pay for what others have chosen! (Interviewee 16)

Thus, the context of path dependency emphasizes the importance of consistent product-process development which is most accurately expressed by the term 'planning with the end in mind' (Yu 2008). In the context of path dependency, interviewees were concerned with creativity in product development being limited by production constraints. In

addition, some decisions made under given information can be erroneous or counterproductive under additional information at later stages—an example where path dependency can have a negative impact. Iterations and a dynamic conception of process development may countervail this effect. Hence, iterations are the foundation for risk assessments and improvement of the quality of product and process.

> It is not possible to discuss everything beforehand as environmental conditions change over time. Therefore, process development must be defined in a dynamic way that allows for flexible responses when errors occur. (Interviewee 8)

In fact, developers reported being emotionally attached to development outcomes, which substantially complicate error detection. In sum, the interface as well as finding the right transfer moment seem to be a bit arbitrary, based on experience and learning-by-doing. One of the most important criteria defining the right point of transfer between product and process is feasibility and market potential. Furthermore, it is important that each actor knows the guidelines and limitations of the other to be able to communicate a feasible process.

4.2.2 Project attrition rates

For companies in biotech developing a portfolio of new products it is necessary to gain early cash flows, enhance external visibility and legitimacy, attain early market share, and sustain in the long run (Schoonhoven et al. 1990). The second factor addresses the degree of uncertainty inherent to multi-project environments. Multi-project environments refer to the parallel execution of similar development projects with later prioritization depending on the progress of each project. Process developers emphasize attrition rates as major sources of uncertainty in multiple project environments. This uncertainty concept contrasts with the previous dimension of uncertainty which implied that higher uncertainty is successfully accompanied by stronger integration. The first dimension focuses on single projects and does not account for attrition rates which occur as major challenges in multiple project environments. Projects in biotechnology are usually confronted with particularly high attrition rates and thus the majority of projects are never completed.

> The prioritization of the overall project. From a global perspective, we have about 60-80 projects at the same time. This is, of course, much more than we can actually handle. And this leads to a constant annoyance and bargaining about resources. That is in the best case ideally we would have a list where we say these 60 projects are ranked according to specific criteria and we know exactly where we start and where we have no more resources. (Interviewee 10)

High attrition rates increase the risk of investing in projects which are doomed to fail anyway. This finding is confirmed by looking at different types of products. On the one hand, the development of new active pharmaceutical ingredients is associated with high attrition rates. Thus, process development is integrated as little as possible in early stages in order to quickly and cheaply reach the first clinical trial. On the other hand, the development of biosimilars is associated with low attrition rates. Thus, process development is highly integrated before the first clinical trial in order to avoid costly rework.

> If you look at biosimilars where the development is relatively riskless, I [process developer] invest at the early stages in order to ensure from the beginning that my

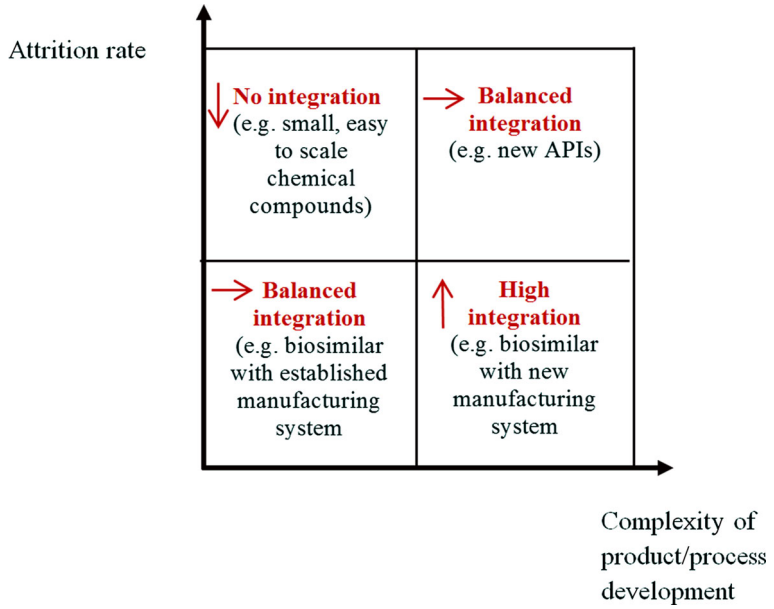

Fig. 4 Integration according to the two types of uncertainty (own figure)

product is similar or identical […] and we save time and money at the end. (Interviewee 26)

As already indicated in Fig. 2, it is important to notice that the attrition rate does not result in a linear decline of projects but rather an exponential decline. This implies that earlier involvement of process development is associated with an exponentially higher risk of investing in projects which will be abandoned at a later stage. Given fixed development capacities, this also means that less effort remains for the most promising projects.

Figure 4 provides a summary of the two uncertainties and the respective influence on product and process development integration.

4.3 Standardization as mechanism for product-process transfer

Standardization has been described as knowledge and technology transfer activity that supports new product development (Großmann et al. 2016). Using and integrating prior knowledge into so called 'platform technologies' in turn facilitates standardization. Particularly, in the light of several concurrent NPD projects, the objective is to generate a transferable process understanding which can be used in multiple problem settings. Hence, during the development of products, platform technologies serve as repositories of knowledge where either new knowledge is added to the knowledge base or the existing knowledge base can be easily accessed (Großmann et al. 2016). Integrative data and knowledge management is a precondition in order to convert experience into higher product quality and shorter time-to-market. Additionally, platform technologies can help to overcome technological complexity. Practitioners confirm the benefits of such platform technologies with regard to speed and efficiency.

> If we really have a deeper understanding of such a process, then we call this a platform technology. This is actually a kind of toolbox, which can be recalled again and again, if a specific problem or a certain task results and then we can draw on what is already known. They are also so well studied and understood that one can make adaptations according to the needs very quickly. These are, so to speak, platform technologies and platform processes, which are then used to get through phase one as quickly as possible. (Interviewee 20)

The interviewees state that platform technologies facilitate process development and significantly reduce cost and time but they also raise negative aspects of this form of standardization.

> When I say I prescribe to a platform and to the efficiency in terms of risk minimization, then I naturally close myself to a certain degree of innovation that perhaps I no longer allow at this point. (Interviewee 15)

In biotech, firms need to strike a balance between both flexibility and standardization. There needs to be the right equilibrium between the two to allow for the creativity that biotech firms in contrast to pharma firms are known for but at the same time ensure an efficient transfer and scale-up (Liker et al. 1999). Despite the fact that standardization can be useful for process innovation, it might not be feasible in all contexts as the novelty of the technology might mitigate that positive effect of standardization (Brem et al. 2016). Previous research has shown that standardization might work well in the context of minor or incremental new technologies that need to be transferred from product to process development. However, radical technologies are by definition new-to-the-world and more difficult to transfer. Hence pre-defined platform standards cannot be easily applied (Brem et al. 2016). Additionally, the respondents highlight that certain aspects need to be standardized to achieve optimal product quality and pureness. Therefore, a minimum of quality management and *product quality standards* are widely established in biotech companies.

> For the product quality […] a few minimum standards must be observed. That must be achieved. So a certain purity, of course, the activity must be high enough. But that is relatively fixed. (Interviewee 26)

Since biotech firms operate in an environment where they need to show evidence that their processes work on human-beings during clinical trials to eventually receive FDA approval, they need to perform standardized processes. Thus, everything that is connected with the process and the subsequent approval must be clearly documented. The quality of the data management is critical for the delivery at the end.

Finally, the respondents point out that documentation for the transfer itself is imperative. Particularly, they argue that *standardized transfer protocols* allow for the coordination between individual people and help to overcome communication issues as well as geographical distance. Reasonable logging and recording is needed to inform the people involved because not always everyone is present at any time.

> So it is standardized to the extent that it is clear which information, which work packages, and which knowledge is transferred. This is all documented. (Interviewee 15)

In sum, process standardization in terms of platform technologies, product quality monitoring and standardized transfer protocols becomes ever more important in biotechnology. Harmonization and standardization, however, also depend on the firm's age, the

evolution of routines over the firm's life cycle as well as the experience of (R&D) managers. In terms of standardization interviewees mainly talk about routinized stages and coordination mechanisms written down in templates coordinating the development efforts or knowledge codification mechanisms that help guide and inform developers. Some managers acknowledge the importance of these standards, others do not have anything in place arguing for the innovativeness of biotech that might be limited through standardization.

Some interviewees doubt the benefits of standardization due to the inherent complexity of product-process development in biotech.

> Is it always like that, when you transfer a method to another lab, there are always problems. Even if you write really good SOPs [standard operating procedures], which map the process down to the last detail, there are nevertheless problems. (Interviewee 22)

5 Discussion and conclusion

The transfer from product to process development is a critical success factor and a highly complex development stage within NPD. The interface between product and process development relies on many contingency factors and is characterized by high interdisciplinarity as well as high uncertainty. Our study provides a model of the technological, operational and organizational boundary conditions in the transfer from product to process development. Based on 31 interviews with experts in biotechnology, we find that in addition to the three influencing success determinants discussed by previous literature, in this particular context, relational and market determinants to be critical for a smooth transfer and/or integration between product and process development. We add these two additional determinants to the framework developed in Sect. 2. Particularly, market determinants, such as customer specifications, competition and regulatory constraints can have a huge impact on the successful transfer from product to process development. Relational determinants have also been underexplored by previous literature despite the fact that the human factor, interpersonal relationships and trust significantly impact a smooth transfer from product to process development.

Additionally, this study provides recommendations for achieving a better transfer between product and process development.

The new framework disentangles five key influences for the quality and productivity of the beginning of process development:

- Firms in biotechnology face severe technological complexities that can limit or influence product quality. Thus technological complexity is an important contingency for the transfer from product to process development.
- A smooth transfer is further stimulated by experienced staff, sufficient resources, a realistic timeframe and efficient communication between the different organizational units.
- Organizationally, firms can influence the transfer by establishing an open and communicative firm culture, low spatial distances between product and process development and clear structure and definition of responsibilities between the subunits.

- Given the transient nature of process development at the front end, process developers must constantly reevaluate their development activities in view of contextual conditions, such as production constraints, competition and market requirements.
- Actors must be aware of the high attrition rates resulting from multi-project management and the interplay between the development units as a source for uncertainty. Awareness is the precondition for efficient governance of the interface and overall objective alignment.
- Platform technologies are a medium to overcome discontinuities across the boundaries of process development. Codified knowledge in the form of standardized operating procedures complements these platforms.

These results allow us to improve existing contingency-based models of product-process development and put forward new influencing variables. We suggest a perspective on the development process that focuses on technological consistency, enhanced interpersonal relationships, communication and standardized knowledge management, which in turn supersedes more costly personnel integration mechanisms and eventually increases the performance of new product development.

While organizational mechanisms of personnel integration have been extensively researched in the past (Moenaert and Souder 1990), standard operating procedures (e.g. transfer protocols) and platform technologies offer great potential for smooth transfers, although they have been underexplored in the context of product-process development. Consistent development implies that tasks and objectives of process development are already motivated to be conducted within product development. Therefore, standardization can also reduce complexity and leverage investments along the innovation process (Krishnan and Gupta 2001). Our findings are in line with Großmann et al. (2016) who argue that standards serve for transferring codified idiosyncratic knowledge within and outside the company. Furthermore, standardization facilitates technology transfer by providing privileged access to interdisciplinary knowhow (Großmann et al. 2016). Through this seamless coordination product and process development benefit by avoiding costly (additional) integration mechanisms. One particular challenge for consistent development is to monitor product quality across functional units. Therefore, a standardized analytical methodology must be established which is capable of quickly determining product quality at all different scales.

5.1 Limitations and further research

This study is a first attempt to disentangle the complexities at the interface between product and process development. Case studies are by definition limited in their sample size, and more research is required before stating more definitive conclusions. Our study represents a starting point in this line of inquiry, but it is not the end to it all. Detailed quantitative studies are still needed to further generalize the results. Since the data sample represents only one very specific industry, the results might not apply to other industry settings such as electronics or automotive where development cycles are much shorter. The biotechnology industry is characterized by dynamic, interdisciplinary development tasks, long development times and open innovation. Nonetheless, these characteristics are also found in many other high-tech industries. Therefore, we argue that the findings might be transferable to other highly complex and relatively young industries such as nanotechnology. As a result, this conclusion must be drawn with the significant caveat that not all science-based sectors are the same, and the lessons from biotech may not apply more broadly. Clearly,

this issue merits further research as it has significant implications particularly for the management of development projects and processes. Previous studies have been conducted on the single project level while overlapping of development activities in multi-project environments has often been neglected (Gerwin and Barrowman 2002). In a multi-project environment, an earlier involvement of process development potentially increases the number of running development projects. Therefore, integrated process development cannot be properly investigated without accounting for aspects of the R&D project selection process (Oral et al. 1991).

Furthermore, the study could be prone to a country-bias as 24 out of 31 interviewees refer to a German-speaking work environment, including Austria and Switzerland. However, 7 interviewees are based in biotech firms operating in Canada, Great Britain, Mexico, the Netherlands or the United States that reveal similar patterns. The only notable difference between the companies interviewed in Europe and the US for example goes back to the failure culture that many US (biotech) firms have which makes them overall less risk-averse and more open for experimentation. This is particularly useful in the high risk environment of biotechnology. Overall, there are some structural differences between biotech firms in Europe and US regarding their capital endowment, failure tolerance, investment rounds, and the appreciation for new products but regarding the optimization of product and process development our study did not reveal any major differences.

Additionally, this study did not address further influencing factors such as leadership characteristics which opens up interesting avenues for future research. Particularly, the influence of management preferences for organizational structure and the implementation of the interface can be a fruitful area of research. Moreover, the concept of sociocultural distance between product and process development needs to be broken down into more detailed contingencies in order to provide a complete understanding. What are the main drivers for this distance: educational background, age, experience, incentive systems, etc.? The interviewees further point out that the end of process development and the beginning of the production phase also constitutes an ambiguous interface. However, in this paper we do not account for the challenges regarding the often highlighted second interface: the end of process development.

Although the findings indicate that standardization is an additional powerful tool in comparison to classical personnel integration mechanisms, it remains still unclear how these two approaches can be optimally combined and to which degree one can supplement the other. It remains for further research to quantify the advantage of standardization. According to the interviewees, standardized knowledge management will become the biggest management challenge in the next few years and thus merits further research in the context of biotech product-process development transfer.

5.2 Managerial implications

The findings of our study provide insights for R&D/innovation managers and process engineers by providing tangible illustrations of the interface between product and process development. Concerning the need for a better transfer between product and process development, managers have to account for stronger coordination and better communication between scientists and the respective process engineers. Regular meetings, clear transfer protocols, documentation and assigned roles will minimize goal conflict, sociocultural as well as geographical distance. Thus, it is important that people meet at least once before a new project starts. This significantly reduces the cultural and language barriers if people in product development know who they are dealing with in process

development and vice versa. Moreover, adopting new procedures, and building common languages and norms (Ettlie and Reza 1992) in terms of a shared culture will be beneficial for the overall success at the interface of product-process development. Finally, both product and process development initiatives have to be orchestrated by one central function that supervises the progress and can coordinate when the product is ready to move to the next stage. Furthermore, this function can then also identify weaknesses and bottlenecks in the transfer process.

Top managers supervising developers in the NPD process can draw conclusions for the optimal organizational structure of the interface between product and process development. Particularly, in cases where the basis of the process is not clear or is still in a very conceptual phase and the researcher has only wild assumptions about the best way of manufacturing a compound or protein, parallel work between product and process developed can be extremely dangerous. Research must simply have the opportunity to try things out and be creative before the new product will hit the next level. This trial-and-error phase during product development allows for a spontaneous idea or experiment, which shows whether the researcher is completely off the track. If that is the case, then the researcher can eradicate his/her error within a day which would be more complicated if process development is already on-going. Hence, this possibility for trial-and-error is, if one parallels strongly, basically taken away. So therefore a very clear credo is, that if neither the basis nor the basic design are entirely clear, researchers and engineers should not work in parallel.

While 'cross-functional teams' and 'personnel integration' have been frequently investigated bridging mechanisms in the management field for a long time, the transfer between development units can be improved by moving from integrated to standardized development. In the future a challenge for managers will be to engage in standardization as well as use knowledge management tools which should be organized in modules that can be rearranged depending on the development requirements. Additionally, standardizing how information is shared and providing central access to relevant information to all actors involved in product-process development helps to guarantee a smooth transfer. For achieving these goals, people have to be trained and understand the importance and benefits.

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