Paper to be presented at the

35th DRUID Celebration Conference 2013, Barcelona, Spain, June 17-19

Integrating the Front End of Process Development: An Exploratory Investigation

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Abstract

Process development is the link between inventions and full scale production. While the start of new product development has been researched extensively and is often referred to as the 'fuzzy' front end, only few studies have investigated the beginning of process development. The objective of this paper is to investigate how the front end of process development integrates with new product development. Drawing on in-depth interviews in the biotechnology industry, in a first step we break down the tasks and organizational settings at the beginning of process development. Following these results, we provide a conceptual framework about the interdependencies between product development and process development. Subsequently, uncertainties with respect to development stage, socio-psychological distance and multiple project environments are discussed in view of a holistic optimization of the transition from product development to process development. Finally, quantitative as well as qualitative results indicate that consistent development platforms are a beneficial medium for successful integration of process development, while rather mixed results are found for personnel integration, such as cross-functional teams.

Jelcodes:O32,L65

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ABSTRACT

Process development is the link between inventions and full scale production. While the start of new product development has been researched extensively and is often referred to as the 'fuzzy' front end, only few studies have investigated the beginning of process development. The objective of this paper is to investigate how the front end of process development integrates with new product development. Drawing on in-depth interviews in the biotechnology industry, in a first step we break down the tasks and organizational settings at the beginning of process development. Following these results, we provide a conceptual framework about the interdependencies between product development and process development. Subsequently, uncertainties with respect to development stage, socio-psychological distance and multiple project environments are discussed in view of a holistic optimization of the transition from product development to process development. Finally, quantitative as well as qualitative results indicate that consistent development platforms are a beneficial medium for successful integration of process development, while rather mixed results are found for personnel integration, such as cross-functional teams.

1. INTRODUCTION

High income countries can preserve their wealth through high levels of innovativeness. However, inventive talent on its own is not enough to maintain a comparative advantage. Only those which are capable of transforming discoveries and prototypes from the scientific laboratories into marketable products will profit from their inventiveness. In this line of thought, the new product development (NPD) literature commonly differentiates between product development and process development (Brown & Eisenhardt, 1995; Pisano, 1997). While product development refers to design or discovery of new products (upstream activities), process development is concerned with manufacturability (downstream activities).

In the current paper we focus on the interface between product development and process development, which has been sparsely researched in the past (Kurkkio, Frishammar, & Lichtenthaler, 2011). Firms often assign product development to the research department and process development to a separate development department, although a clear cut between the contextual tasks is not possible. De facto, the transition from product to process development must be considered a gray scale. Furthermore, it has been shown that new products generally rely on a combination of product innovation and process innovation (Utterback & Abernathy, 1975). Therefore, a complete understanding of the interface between product development and process development is a precondition for an efficient design of NPD.

Integration and interdependencies of development activities are widely acknowledged as crucial success factors in NPD (Gerwin & Barrowman, 2002). However, existing literature shows that attention is mainly given to product development, while a lack of awareness for process development is noticed. Scalability of an invention or scale-up of production is often not even recognized as potential pivotal bottleneck for the successful implementation of innovation (Pisano & Wheelwright, 1995). Similar concerns hold for the R&D/Production interface in comparison to the R&D/Marketing interface, where much more effort has gone into

examination of the latter (Song, Montoya-Weiss, & Schmidt, 1997). This is also reconfirmed by the managerial perspective, where innovation is associated with product development, i.e. product development is highlighted, while the complexity of process development is understated. For example, Lu & 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.”

Few authors already tried to formulate a standardized model/procedure of process development (Hayes, Pisano, Upton, & Wheelwright, 2005; Ulrich & Eppinger, 2004), but especially the interdependencies of process development with product development are not yet understood. Interdependencies gain in relevance as process development increasingly depends on innovation networks (Freeman, 1991). In summary, the aim of this paper is to answer three fundamental questions: Which activities at the beginning of process development are integrated? Which uncertainties influence the design of the integration? How can the transition from product to process development be facilitated?

Following these three questions, we investigate the front end of process development in three steps. In a first step, we examine the tasks and organizational settings at the beginning of process development as well as the interactions between the functional units. In a second step, different types of uncertainties with regard to the interface between product development and process development are discussed and compared. In a third step, means of integrating process development are evaluated.

2. THEORETICAL BACKGROUND

2.1. TASKS AND ORGANIZATIONAL SETTING AT THE BEGINNING OF PROCESS DEVELOPMENT

The beginning of the innovation process, which refers to the start of product development, has been popularly coined as “fuzzy” due to its ill-defined starting point. Several qualitative

studies have examined the influencing factors of this critical phase (Khurana & Rosenthal, 1998; Koen et al., 2001; Montoya-Weiss & O'Driscoll, 2000). The front end of product development is mainly characterized by its experimental work, high uncertainty about outcomes and disproportionate effects of decisions during this phase. The nature of activities at the start of product development generally show great variance and rely on interdisciplinary expertise across organizational boundaries. The beginning of process development differs from the front end phase of product development with regard to key characteristics, such as scope and form of interdependencies (Pisano, 1994). However, the current paper draws on the findings of the "fuzzy front end" in product development as a starting point.

For the purpose of our analysis we adopt a multidisciplinary view of innovation combining technological, operational and structural aspects of NPD. We assume the perspective of Clark & Fujimoto (1991) who define NPD as processing of information in order to characterize interdependencies. Thus, development activities are regarded as entities which receive input information from preceding activities and convert it into output information for successive activities. This concept has been adopted by other researchers and is widely acknowledged (e.g. Gerwin & Barrowman, 2002; Krishnan, Eppinger, & Whitney, 1997). On this basis, we present a conceptual framework of the development activities which also builds on the resource-based view of the firm by accounting for development capabilities (Tatikonda & Montoya-Weiss, 2001).

The organizational setting, in which NPD is embedded, shows great variability and has still not been completely understood (Brown & Eisenhardt, 1995). Especially overlapping process development with product development and seeking optimal degree of overlapping requires mutual understanding about the beginning of process development. An ill-defined starting point of process development bares the risk that functional tasks and objectives of process development do not match with the ideal organizational structure of the innovation process.

Proposition 1: *Identification of the influencing factors at the ill-defined starting point of process development is a prerequisite for efficient integration.*

2.2. Uncertainties in the Integration of Process Development

The concurrent engineering literature is concerned with integration and overlapping of development activities (Gerwin & Barrowman, 2002; Krishnan & Ulrich, 2001; Takeuchi & Nonaka, 1986). The nature of product development and process development imply a sequential succession within the innovation process, but several empirical studies have indicated that overlapping development activities can lead to superior outcomes (Clark & Fujimoto, 1991; Eisenhardt & Tabrizi, 1995; Terwiesch & Loch, 1999). Ettlie (1995) has provided a first quantitative study of product-process development integration. Based on a mailed survey, Ettlie has shown positive correlation between integrating process development and higher sales per employee. However, he wasn't able to show that integrated product-process developments have shorter development periods.

On the basis of mathematical models Krishnan et al. (1997) and Loch & Terwiesch (1998) have investigated contingencies in terms of trade-offs in order to determine an optimal degree of overlapping. They have shown that more overlapping does not inevitably lead to superior outcomes. Instead, dependent on task characteristics and level of uncertainty different degrees of overlapping are ideal.

Environmental uncertainty also influences the structure of an organization (e.g. Lawrence & Lorsch, 1967). Thus, Gupta, Raj, & Wilemon (1986) have pointed out by means of uncertainty reduction theory that high environmental uncertainty increases the perceived need for integration at the R&D/Marketing interface. Depending on the level of uncertainty two questions evolve for every interface: Firstly, when should process development engage in product development? Secondly, how should process development engage in product development?

This suggests a two-dimensional perception of overlapping which distinguishes between duration and form of integration.

The influence of uncertainty has often been defined as market uncertainty or engineering changes during the project (Koufteros, Vonderembse, & Jayaram, 2005; Loch & Terwiesch, 1998). Two research gaps with regard to uncertainty are identified in the literature. On the one hand, Song & Montoya-Weiss (2001) claim that uncertainty of NPD projects in connection to firm-level factors, such as organizational culture or structure, have not yet been investigated. On the other hand, previous studies have been conducted on the single project level while overlapping of development activities in multiple project environments has often been neglected (Gerwin & Barrowman, 2002). In a multiple project environment an earlier involvement of process development also increases the number of potential development projects which are still alive. Therefore, integrated process development cannot be properly investigated without accounting for aspects of the R&D project selection process (Oral, Kettani, & Lang, 1991). The current study approaches the theme by introducing the attrition rate or survival rate respectively as a contingency.

Gupta et al. (1986) have already shown with regard to the interface between R&D and marketing that sociocultural differences are another source for uncertainties. Ettlie (1995) has also stated “empathy across the interface is a key factor in determining effectiveness” but does not further investigate the issue. We assume for our analysis that a larger socio-psychological distance between product and process development decreases the willingness to overlap and increases the uncertainty in determining optimal integration mechanisms.

Proposition 2: *Uncertainties beyond incomplete information within the development project must be considered to determine the ideal point in time and the most effective mode of integration.*

2.3. MEANS OF INTEGRATION

The form of integrating mechanisms varies widely across different organizations (Ettlie, 1995). So far, considerable effort has gone into examination of organizational techniques for integrating development units. Van de Ven & Delbecq (1974) already researched organization and coordination methods in the collaboration of different units within one firm. Then, Adler (1995) conducted a first analysis about product - process coordination methods from an organizational perspective. He has used the production example of printed circuit boards for electronic assemblies and hydraulic tubing for aircrafts. Based on contingency theory, Adler has developed a two-dimensional model depending on novelty and analyzability of the product / process fit. Major drawbacks of Adler's paper are the strong assumptions: On the one hand, actors must be aware of the interdependencies between product and process development. On the other hand, actors must be willing to implement the proposed coordination methods. We use Adler's work as a basis for our analysis. In particular, we critically examine his assumptions with regard to the coordination methods.

Recent publications have emphasized that benefits of concurrent engineering can be offset by integration costs such as communication time (Lin, Qian, Cui, & Miao, 2010). Nevertheless, little attention has been paid to platforms which are capable of providing a seamless transition from product development to process development. Ettlie & Reza (1992) indicated in a study of plant modernization that the utilization of new flexible manufacturing systems is also significantly correlated with the integration of design and production activities. The current paper investigates technological platforms as alternative or complement to the personnel integration mechanisms as advocated in the organizational coordination methods.

Proposition 3: *Technological platforms can be used as an effective medium for seamless and consistent integration between product development and process development.*

3. METHODS

The proposed analysis requires a combination of different methods. Main objective of the paper is the identification of causal relationships and theory building with regard to the front end of process development. Given the complexity of the front end as well as the exploratory nature, multiple case studies have been conducted in order to achieve high methodology fit (Edmondson & Mcmanus, 2007). The cases were evaluated based on qualitative and quantitative methods which allows for cross-checks in order to validate newly generated hypotheses. Advantage of such a mixed method is the combination of theory building and theory testing (Creswell, 2002; Tashakkori & Teddlie, 2002). Main constrain is the time-consuming process of gaining access to suitable professionals, dealing with formal requirements such as confidentiality, and preparation of data.

3.1. DATA COLLECTION

Triangulation of evidence and validity of results were ensured through different data sources (Dahlander & Magnusson, 2005; Yin, 1984). In the period between December 2011 and October 2012 a total of 31 in-depth interviews in 21 different institutions in the biotechnology industry were recorded. On average an interview took 1 hour and 17 minutes. The longest interview was 2 hours and 30 minutes and no interview was shorter than 30 minutes. Each semi-structured interview was prepared by an extensive web search and accompanied by personal notes. Confidentiality was guaranteed to all discussants. Additional secondary data such as regulatory guidance and best practice reports was accumulated along the research project.

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 (Eisenhardt, 1989; Glaser & Strauss, 1967). Potential interviewees were

approached under the title „Interface between product and process development“. As a starting point, suggestions by a university chair for bioprocess development were used to identify potential experts. Successively, further experts were identified through snowball sampling, where respondents recommended personal contacts. In addition, experts at bioproduction conferences were contacted and follow-up interviews were arranged. Given the personalized sampling strategy, interviews were conducted in a cooperative and open-minded environment.

The semi-structured interviews were based on an interview guide, which divides into five sections. The first two sections are concerned with personal data and general set-up of the interviewed institution respectively. While the third section addresses issues of process development as a whole, the fourth and most extensive section questions the interaction between product and process development. At the end, in the fifth section, a case study is conducted for the last transition between product and process development which the interviewee experienced. The first four sections mainly consist of open ended questions. The last section also contains quantitative questions based on a Likert-type scale with 5 response categories. Before the 31 semi-structured interviews, unstructured interviews were conducted to revise the interview guide. In general, all participants were asked to give concrete examples and explanations from their personal work environment in order to gain an impression as close to reality as possible.

3.2. Sample Description

In order to address the particular influence of contextual technologies, we have chosen the biotechnology industry as subject for our research design. The biotechnology industry is a particular convenient example for an innovation economy which encounters severe problems in transforming ideas and scientific findings into viable products, processes, or services. The NPD process in biotechnology is exceptionally time consuming and costly (Azoulay, Repenning, & Zuckerman, 2010; Pisano, 2010). Development times in industrial biotechnolo-

gy range from 2 to 3 years and in medical biotechnology take up to 15 years (Jungbauer & Göbel, 2012). Furthermore, the NPD process takes place in an open innovation setting (Bianchi, Cavaliere, Chiaroni, Frattini, & Chiesa, 2011). Technology transfers across organizational boundaries take place and services like media optimization are outsourced to contract research organizations (DePalma, 2007). Powell, Koput, & Smith-Doerr (1996) emphasize that due to a complex and expanding knowledge base in biotechnology the locus of innovation can only be found in networks.

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

The sample can be differentiated into experts from industrial and medical biotechnology, which are the two most important branches in biotechnology. Product and process developers from different hierarchy levels are contained in the sample so as to avoid a one-sided account. Furthermore, based on the years of affiliation respondents were sufficiently familiar with their organization to provide detailed information about the specific NPD process. Noteworthy is the broad heterogeneity of the sample with regard to the educational background of the interviewees[1]. 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 interaction between product and process development. The sample is also diversified 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

[1] A tabular overview of all respondents is given in the appendix.

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.

3.3. Data Analysis

Ragin (1994) describes research as a dialogue between idea and proof. In this spirit, the data analysis combines inductive and deductive reasoning. The conjunction of the two can also be described as retroductive approach (Downward & Mearman, 2007). Practical implementation of this approach mainly reflects in coding of the data. In-depth interviews were transcribed immediately after the meeting and coded within supportive software[2].

Based on a literature review and unstructured interviews beforehand, a basic structure of main catchwords was established. The primary coding scheme was then extended or verified while coding the first interviews in order to guarantee a high compliance with reality (Strauss & Corbin, 1994). An initial coding scheme was iteratively developed and then further refined along the analysis. The conversion of descriptions by practitioners into a holistic concept requires deep contextual understanding of the research topic. Therefore, in analogy to papers with similar methodology, all results are illustrated by considerable quotes from the practitioners (e.g. Azoulay et al., 2010). Actual quotes in combination with the predefined approach to data collection, coding and theory building are designed to ensure objectivity and validity of the results.

[2] The software ATLAS.ti version 6.2 was used for coding.

4. RESULTS

In analogy to section two, the main findings are organized in three subsections: Firstly, a contingency framework provides an overview of the influencing factors at the beginning of process development in view of integrating into product development. Secondly, important trade-offs dependent on uncertainties are presented. Finally, the role of platforms is assessed and two short case studies illustrate the challenge of discontinuities along the development process.

4.1. FRAMEWORK OF INTEGRATED PROCESS DEVELOPMENT

A close examination of the beginning of process development reveals the convoluted nature of the interface. It is affected by four main categories: organizational subunits, project progress, tasks and information flow, as well as external influences.

Organizational units. The organizational setting of the front end as indicated by the allocation of the organizational subunits shows great variance across firms. 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. Therefore, these two subunits are assigned to either product development or process development often due to historical reasons.

A similar pattern can be observed with regard to the end of process development which shows great interference with the beginning of production. Process control and process troubleshooting are assigned to either process development or production. In total, six organizational subunits are identified which are also further subdivided or condensed depending on the firm characteristics (see fig. 1).

The organizational setting also relies on environmental conditions, such as time and cost constraints. For example, if patent filing is time-critical due to competition or large amounts of initial investments are not affordable by the project owner, then subsequent rework during

process development is deliberately accepted and product and process development are less integrated. The latter example is a particular challenge in medical biotechnology where small start-ups don't have the financial capabilities to implement a holistic development approach. Instead, product development milestones are accomplished at the cost of the prospective manufacturing process.

> *"If I want to be really quick and save resources at the front, I don't look at my cell lines too closely. Then I risk that my cell lines are instable over time. This means, the older my cells and the more often they divide, the less I can produce. [...] I would have to do another sub-cloning or change my cell line at a later stage because I cannot produce enough material for the market."*

> *"Small firms are mostly financially constraint and quickly have to reach the first phase with little money. [...] If you come through the first phase, you receive fresh money and it is no problem to invest more money into development. Large companies might have a different approach."*

Project progress and information flow. Tasks and objectives at the front end of process development are manifold and substantially change as process development matures. Interdisciplinary activities such as theoretical modeling, statistical analyses, computer aided roboting, as well as manual work in the biotech laboratory are performed.

The main challenge in early process development is the definition of product characteristics and quality attributes against the background of a production environment. When this approach is consistently implemented up to the manufacturing or large scale, 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. In a more general setting, aside from biotechnology, the production strain can also be referred to as the 'production system'.

A conjoint analysis of the mentioned aspects inevitably leads to an iterative process. Based on suggestions by the *Quality by Design* (QbD) initiative, the development activities should eventually result in the identification of *Critical Quality Attributes* (CQA), i.e. most influential physical, chemical and biological product characteristics (Rathore & Winkle, 2009). The QbD approach is strongly recommended by public authorities, such as *U.S. Food and Drug Administration* (FDA) and *European Medicines Agency* (EMA). Thus, QbD more and more coins NPD in biotechnology. The identification of CQAs rests upon the 'assessment of correlations'. Conjointly 'process characterization' determines the *Critical Process Parameters* (CPP). A combination of CQAs and CPPs results in the so called 'design space' which defines the boundaries for future quality and production characteristics (CMC Biotech Working Group, 2009).

External influences. 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 economical constraints and limiting the set of acceptable process outcomes. Prior knowledge becomes particularly important in series of project developments.

In summary, figure 1 presents the various interdependencies between product development and process development which provokes the ambiguous definition of the starting point of process development. The findings reveal that an isolated treatment of product development and process development cannot cope with the peculiarity of reality.

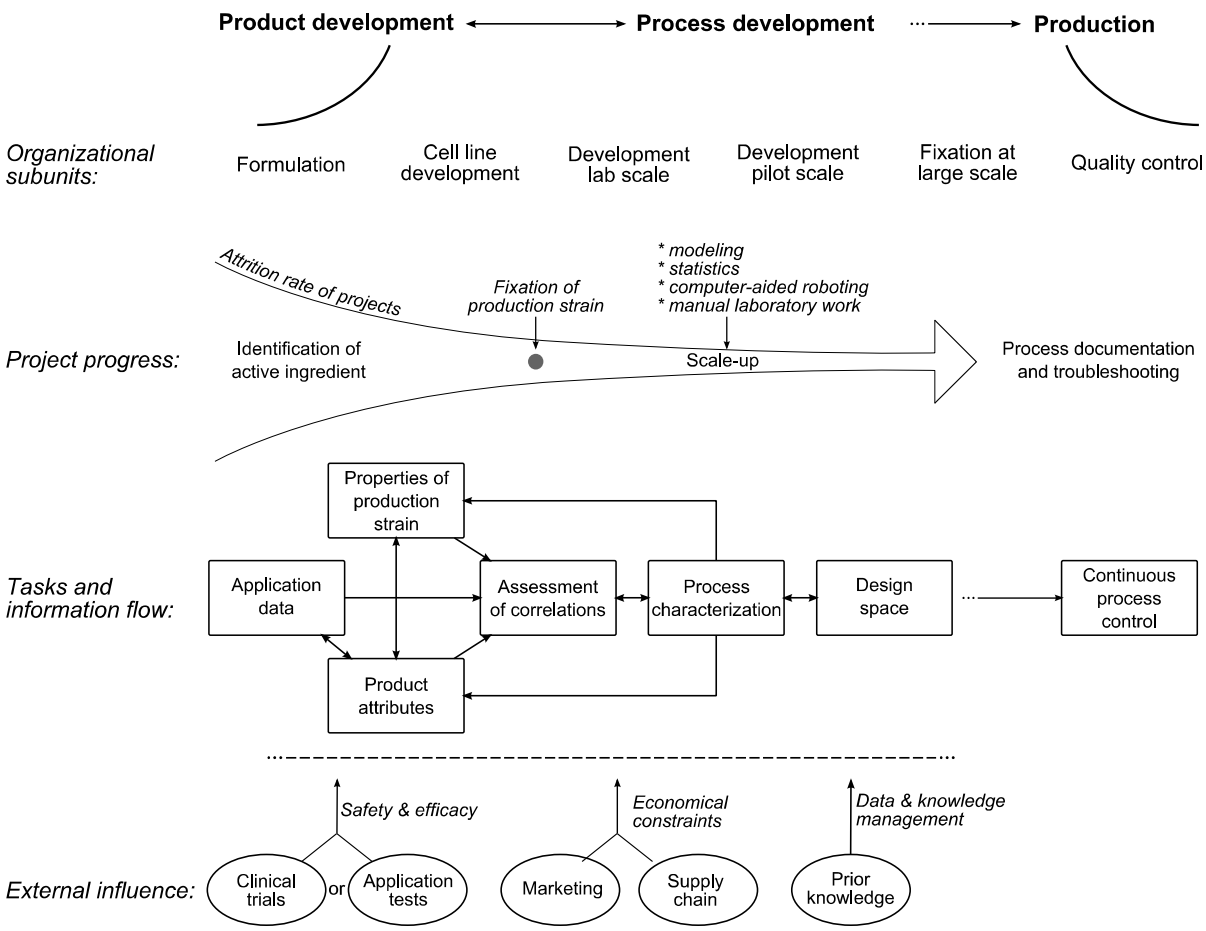

Figure 1 | Overview of the front end of process development

4.2. Implications of Uncertainties

Efficient overlapping weighs up the advantageous and disadvantageous of sequential 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. This means iterations reduce uncertainties with regard to the requirements of the complementary development units. Nevertheless, parallel development is not necessarily associated with optimal development as iterations are time-consuming and costly (Smith & Eppinger, 1997). Under unfavorable conditions, parallel development can be more costly and last even longer than sequential development.

Therefore, it comes as no surprise that the respondents express heterogeneous perceptions with regard to time and content of optimal overlapping (see tab. 1). This underlines the relevance of our research question, especially since firms have become aware of overlapping as influencing parameter.

Table 1 | Contrasting juxtaposition of heterogeneous perceptions

Sequential development	Parallel development
"If I am involved too early and indicate too many process constraints, we miss prospects in product development."	*"Process development must be integrated as early as possible. The earlier, the better!"*
"It is no use to shift a lot of development to the front. It is always the credo: Don't do frontloading and fail early, fail cheap!"	*"Product and process development are strongly connected and process development must be assimilated in product development as early as possible."*

The consideration between the two extreme positions of sequential and parallel development is ascribed to three essential types of uncertainty.

1. Dependencies between product and process development.
2. Socio-psychological distance between the functional units.
3. Attrition rate.

Dependencies between product and process development. As pointed out in section 2, higher uncertainties in the interplay of product development and process development promote an earlier involvement of the downstream activities, i.e. process development. Potential benefits are less rework in later stages and early feasibility tests. In more detail, the development stage at which the main responsibility of a project is transferred is also chosen according to the degree of uncertainty which results from the interplay between the two units. This has an immediate effect for the relevance and complexity of the interface. The band width of organizational structures handing over development projects accounting for iterations is illustrated in figure 2.

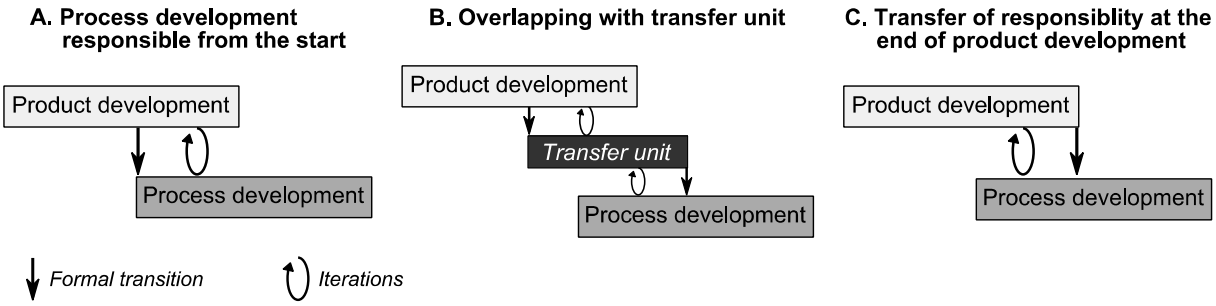

Figure 2 | Organizational structure of overlapping

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 (see fig. 2.A). For example, 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 transition 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 high coordination needs and a complex project transfer (see fig. 2.C) due to accumulated knowledge which has been gathered during the definition of quality attributes and cell screening. The main advantage of 2.C 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.

Thereby, the two alternatives resemble a trade-off between handing over the responsibility too early or too late respectively. A hybrid model is presented in figure 2.B where a separate unit specializes at the gray area between product and process development. This structure comes only into consideration when transfers between product and process development reach a particular frequency.

"This depends on the stage at which the process is transferred. If it is implemented as in our company where we use generic processes at early stages and then we start all over once pro-

cess development starts, half of a day is sufficient for the transfer. If it is a question of a substantially developed process, then it becomes a lengthy transition where people have to communicate and travel in order to properly accompany the transfer. Between these two scenarios, there are many intermediate levels. Of course, in our opinion, we have the best and most efficient solution, but other firms see that completely different."

The objectives for the transfer at the interface can be summarized by two categories: Firstly, product and process requirements linked to the physical host cells are considered as hard transition facts. Secondly, explicit as well as tacit knowledge must be enclosed in the project knowledge base, even when the organizational allocation of the project shifts. Thus, depending on the development stage, breadth and depth of the required content can complicate the coordination between the organizational units.

This organizational challenge points out the problems associated with the 'fuzzy' front end of process development. Strong interdependencies between the functional tasks preclude a clear cutoff point between product and process development which is often confronted with strict boundaries on the organizational level.

Another aspect with regard to this type of uncertainty is the concept of path dependency. Path dependency describes how one particular development outcome realizes based on many subsequent development decisions. Thereby, it explains the phenomenon that small differences in early development stages have unequally large impacts on development outcomes (Anderson Jr. & 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.

In the context of path dependency, integrated process development has two major benefits: Firstly, feasibility studies of potential outcomes can be conducted at an early stage. Secondly,

unfavorable lock-in effects for the production process can be avoided. Both aspects go back to the previously mentioned concept of consistent process development, which is most accurately expressed by the term “planning with the end in mind”.

Path dependency also indicates that too many constraints by process development can be disadvantageous for the development process. Most frequently interviewees were concerned with creativity in product development being limited by production constraints. In addition, path dependency is linked to troubleshooting. This is not necessarily associated with human failure, but decisions made under given information turn out to be erroneous or counterproductive under additional information at later stages. Iterations (see fig. 2) and a dynamic conception of process development countervail this effect. Iterations are the foundation for risk assessments. This is of particular relevance with regard to external partners.

> *“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.”*

Error detection cannot be considered as a completely rational process. In fact, developers are emotionally attached to development outcomes, which substantially complicate error detection. This finding leads to the second type of uncertainty caused by social-psychological distance.

> *“Hopefully errors are detected at early stages, i.e. in the lab or latest in pilot scale. [...] In production there shouldn't be any mistakes because this becomes really expensive.”*

> *“We don't like changes, unless it was our idea. Then we would change it.”*

Socio-psychological distance. 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 also be decisive factors for coordination mechanisms.

Gupta et al. (1986) have pointed out that early involvement in the decision process creates a common bond between the participants. This prevents deadlocked opinions when aligning the requirements and achieves commitment in view of the coordination method. However, implementation of these beneficial effects is far from trivial and missing empathy can lead to blame-placing and conflict (Ettlie, 1995).

Previously mentioned interdisciplinarity can be the source for such sociocultural distance. 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 thoughts 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 shrinks. 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 (see tab. 2): 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 would require. Secondly, the willingness to commit to coordination mechanisms on an emotional level is decreased through large socio-cultural distance due to low appreciation and resentments towards the “other side”.

Table 2 | Quotes linked to sociocultural differences

Relevance	Appreciation
"Process development is extremely important because a huge cost factor depends on it."	*"Process development is a little bit like playing second league."*
"People who are familiar with the matter know that process development is the heart of the product."	*"I regard process development primarily as handcraft. Very few people approach this scientifically."*

Another drawback is that personal factors are also difficult to monitor. An efficient transition can be a very subjective procedure which depends on many soft measures. One potential criterion could be the frequency of contact where length of contact should be neither too short nor too long. The cases have shown that hard performance measurements are commonly established within the institutions but soft measures are rarely accounted for.

"Are all data available? Are the certificates available for new input materials? All of this is checked and standardized, but the question of two people working together productively is not addressed. [...] Interpersonal factors are not monitored systematically."

Multiple project environments. The third influencing factor addresses the degree of uncertainty in multiple project environments. Process developers emphasize attrition rate as major sources of uncertainties in multiple project environments. This uncertainty concept contrasts with the previous dimensions of uncertainty which implied that higher uncertainty is successfully accompanied by stronger integration and overlapping. The first two dimensions focus on single projects and don't account for attrition rates which occur as major challenge in multiple project environments. Projects in biotechnology confront particular high levels of attrition rates and the majority of projects are never completed.

"We probably assume a constant flow of new products which arrive from the research department and are then transferred from process development into production, but this is an exception rather than a rule!"

Higher uncertainties with regard to higher attrition rates cause less integration of process development into product development. This is due to the fact that higher 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 less 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 product is similar or identical [...] and we save time and money at the end."*

As already indicated in figure 1, it is important to notice that the attrition rate doesn't 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.

This described disadvantage of early involvement is partially offset by the beneficial effects of early involvement as indicated by the first dimensions of uncertainty. In combination the three types of uncertainty constitute a local optimum of overlapping.

4.3. Platforms as Medium for Consistent Development

The usage of prior knowledge facilitates the front end of process development. It allows for platform technologies with regard to series of NPD projects. In comparison to other industries, biotechnology so far rarely benefits from the potential of conventional standardized

components, although this is changing at the moment (Henkel & Maurer, 2007). The objective is to generate transferable process understanding which can be used in multiple problem settings. Integrative data and knowledge management is a precondition in order to convert experience into higher quality and shorter time-to-market. Practitioners confirm the benefit of platform knowledge with regard to speed and efficiency.

> *"By now, we use platform processes for standard anti-bodies in order to be quick and efficient in the early phases. It is very advantageous, especially if you do a lot of transfers between sites. Then you don't have to look at new input material and it is easier and faster. [...] We are not at 100 percent, but we made substantial progress in the last 10 years."*

Subsequently to the qualitative part of the interviews, a quantitative questionnaire was answered by the respondents. As dependent variable developers were asked to report on a Likert-type scale, how successful their last transition from product to process development was, where 5 corresponds to 'very successful' and 1 to 'very unsuccessful'. Within the questionnaire developers also answered whether for the last transition an integrated or a rather sequential development approach was chosen. Based on a Student's t-test, figure 3 shows that the average transition success with an integrated development approach is higher than the success with a sequential development approach. However, the two means are statistically not different on a 10 percent significance level (p-value = 0.314). Respondents referred to integrated development mainly by the idea of cross-functional teams, job rotation, and shared responsibility, i.e. personnel integration.

A larger difference between the means is observed for institutions which have implemented a consistent technological development platform across the boundary of product and process development. The two means are significantly different at the 10 percent significance level (p-value = 0.076). This indicates that consistent technology platforms have a substantially beneficial impact in the transition from product to process development. While organiza-

tional mechanisms of personnel integration have been extensively researched in the past, consistent technology platforms provide a larger potential for smooth transitions, although they are rarely studied in the context of integrated development.

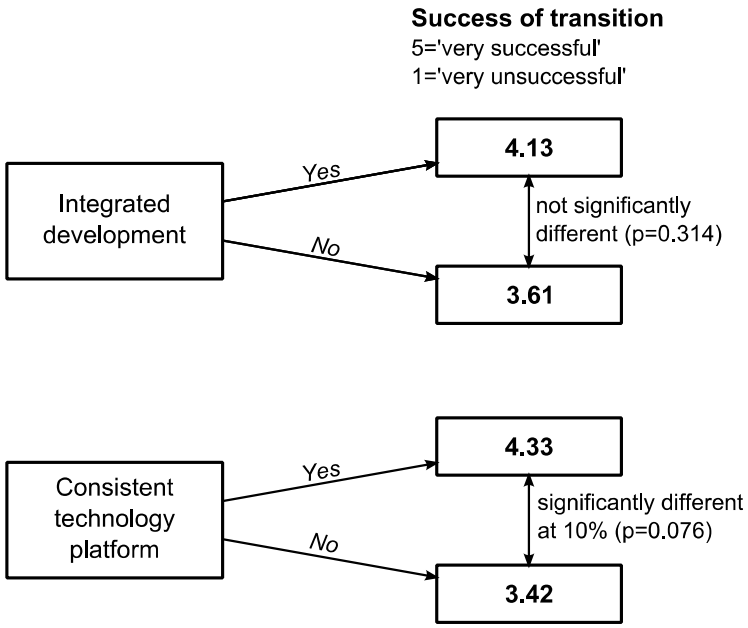

Figure 3 | Comparison of means

Consistent development relies on technological platforms which imply that tasks and objectives of process development are already motivated to be conducted within product development. Therefore, platforms can also be seen as a development approach that reduces complexity and leverages investments along the innovation process (Krishnan & Gupta, 2001). This perspective focuses on the capability of technology platforms to facilitate technology transfer and providing privileged access to interdisciplinary know-how. Through this seamless coordination product and process development benefit by avoiding costly integration mechanisms.

One particular challenge across functional units is project monitoring with regard to product quality. In order to align development efforts, a consistent analytical methodology must be

established which is capable of quickly determining product quality in all different scales. This requires a highly integrative design of the method:

„Product quality must be measurable with an analytical protocol. The analytical protocol is established in the research department because we need it at a very early stage to evaluate product quality. This should be passed on until production."

In the following, two explicit examples illustrate the challenges of discontinuities at the interface. This means that development tools on the product side are not synchronized with development tools on the process side. This causes additional development effort and prolongs the overall development time. In this context the benefits of consistent development platforms can be demonstrated.

1. Human embryonic kidney (HEK) cells are comparably easy to handle in the laboratory, i.e. they are easily transfected and cultivated in a laboratory environment. For this reason HEK cells constitute the foundation for many research projects which rely on mammalian cells. In contrast, at larger scales Chinese hamster ovary (CHO) cells provide the most favorable characteristics and are most widely-used. Thereby, overall development is disrupted.
2. During product development cultivations are usually conducted in shake flasks combined with simple batch-processes. At larger scales cultivations are operated in large fermenters combined with fed-batch-processes which are distinguished by a continuous feed flow. This also impedes a continuous development across the boundary of product and process developments.

The root cause of these discontinuities can be found in partial optimization of single development steps. This means that development tools such as HEK cells are optimal in product development, but don't consider the NPD process as a whole. Transferred to the second case

this means that batch-processes are easier to handle by scientists in the lab, but they don't produce accurate data over the whole development cycle.

5. DISCUSSION

In analogy to the relevance of the fuzzy front end of product development (Verworn, 2009) the transition 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 interdependencies and is characterized by high interdisciplinarity as well as high uncertainty. In this setting our study provides a product-process model which is embedded in the organizational and technical context.

The framework disentangles the tasks and objectives at the front end of process development. In conclusion, three key influences can be summarized for the quality and productivity of the beginning of process development:

- Given the transient nature of process development at the front end, process developers must constantly reevaluate their development activities in view of attrition rate, path dependency, and contextual conditions, such as production constraints and market requirements.
- Protagonists must be aware of the socio-psychological distance and the interplay between the development units as a source for uncertainty. Awareness is the precondition for efficient government of the interface and overall objective alignment.
- Consistent development platforms are a medium to overcome discontinuities across the boundaries of process development. Codified knowledge and standardized procedures complement the platforms.

These results allow us to improve existing contingency-based models of integrated development and put forward new influencing variables as well as causal relations. We suggest a

perspective on the development process which focuses on technological consistency and integrative knowledge management, which in turn at least partially supersedes more costly personnel integration mechanisms and eventually increases the performance of new product development.

Future development tools must concentrate on increasing the predictive power at the laboratory scale without increasing actual costs (see fig. 4).

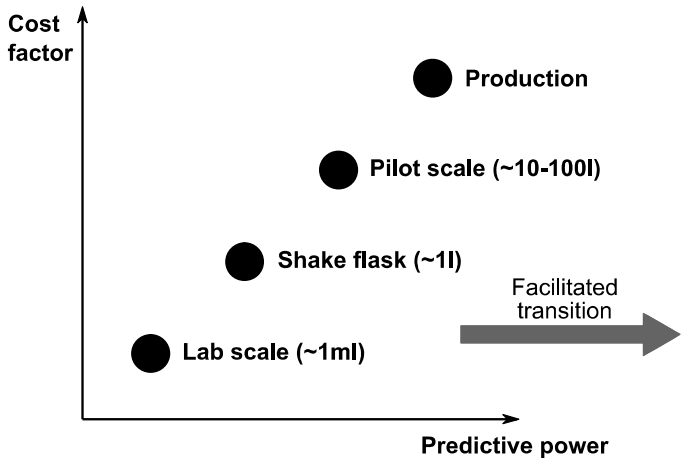

Figure 4 | Predictive Power at Different Scales

According to the definition above, stem cell lines can be seen as an example for a platform technology (Henkel & Maurer, 2010) which facilitates the transition from product to process development. Culturing and maintaining stem cells is difficult and usually established in a time-consuming try and error method. The more people use a particular stem cell line, the better the metabolism of the organism is understood and scientists are able to draw on findings from colleagues. If this experience is made at all scales, the predictive power increases and the particular stem cell line becomes a powerful development platform.

Closely linked to the platform concept is the implementation of an integrative knowledge management. Many of the above mentioned aspects merge within an efficient knowledge management. It provides information independently from organizational boundaries and

across disciplinary gaps. The knowledge management must be structured into flexible modules to serve the dynamic nature of changing specifications. Furthermore, constraints by the prospective production site must be incorporated.

The introduction of consistent platforms combined with integrative knowledge management must also account for socio-psychological aspects. On the one hand, knowledge management must not be reduced to a software solution since software can hardly replace all personal communication. On the other hand, the protagonists must be properly motivated to use the knowledge management as well as the platform. This can only be achieved if the tools are perceived as assistance and not as additional work requirements.

> *"Our reports and data are easily available in a software tool. There you can search for it with key words, but you have to actually do that. It doesn't go without saying that everybody looks for the knowledge, i.e. when you start a new project, you gather what has been done before."*

5.1. Limitations and Further Research

The main purpose of this explorative study is to entangle the complex relations at the interface between product and process development on a conceptual level. Although some of the findings are already reviewed on the basis of statistical tests, detailed quantitative studies are still needed to further quantify the results. Since the data sample is confined to only one industry, we obtain pure and in-depth results, where effects are not counterbalanced due to different industry backgrounds. On the downside, such a specific data sample might come at the cost of losing generalizability of the results. However, the biotechnology industry is characterized by dynamic, interdisciplinary development tasks, long development times and open innovation. These characteristics are also found in many other high-tech industries. Therefore, we assume that the findings are transferable to other industries.

Furthermore, the study could be prone to a country-bias as 24 out of 31 cases refer to a German-speaking work environment, including Austria and Switzerland. However, 7 cases

referred to a work environment in Canada, Great Britain, Mexico, the Netherlands, or the United States and revealed similar patterns.

This study has not yet addressed influencing factors such as leadership characteristics, i.e.: Which influence have management preferences for the organizational structure and the implementation of the interface? The concept of socio-psychological 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 such a distance: educational background, age, experience, incentive systems etc.? Within the framework it is already pointed out that also the end of process development and the beginning of the production phase form an ambiguous interface. However, in this paper only little attention is paid to the challenges with regard to the end of process development.

Although the findings indicate that technological development platforms are a powerful tool in comparison to classical personnel integration mechanisms, it remains still unclear how these two approaches are optimally combined and to which degree one can supplement the other. It remains for further research to determine the preconditions and to quantify the advantage of consistent development platforms. According to the interviewees, integrative knowledge management will become the biggest management challenge in the next few years. This perception seems to be independent from company size or business segment.

> *"Knowledge management is certainly the main topic. How do I properly document the knowledge and how do I integrate the knowledge within the platform. I think this will remain the main challenge."*

5.2. Management Implications

The findings of our study provide insights for process developers with regard to "the other side of the wall". Especially developers from the field of biotechnology find concrete illustrations of the interface between product and process development.

Top managers supervising developers in the NPD process can draw conclusions for the optimal organizational structure of the interface between product development and process development. Technological circumstances are converted to a management level whereby managers are enabled to identify weaknesses and bottlenecks in the transition process. While ‘cross-functional teams’ and ‘personnel integration’ have been buzz words in the management field for a long time, this study shows that consistent development platforms have a larger impact and should be emphasized by managers facing technological discontinuities. With other words, the transfer between development units can be improved by moving from integrated to consistent development.

In the future a challenge for managers will be to provide technological platforms as well as knowledge management tools which are independent from the development scale, from specific individuals and from contextual development conditions. The latter one means that consistent platforms and knowledge management should be organized in modules which can be rearranged depending on the development requirements.

> *“Today it is as follows: 'You don't know how this works? Go and ask him, he works here for 30 years, he knows how it works!' [...] We must head for a tool to structure this knowledge precisely because the goal is to be independent from individuals.”*

APPENDIX

Table A.1 | Overview of Respondents

Position	Duration	Affiliation [Years]	Educational Background
Industrial biotechnology			
CSO / CTO	1 h,36 min	19	Biochemistry
CEO	40 min	4	General engineering
Project Leader	1 h, 39 min	2	Microbiology
CEO	55 min	8	Biotechnology
Principle Scientist	50min	11	Biochemistry
Project Leader	1 h, 32 min	15	Chemical engineering
Project Leader	1 h, 15 min	7	Biotechnology
Group Leader	1 h, 23 min	5	Chemistry
CEO	2 h, 25 min	3	Chemistry
Project Leader	47 min	3	Chemical engineering
Project Leader	1 h, 8 min	19	Microbiology
Group Leader	1 h, 14 min	4	Chemical engineering
Professor (with tenure)	1 h, 16 min	10	Chemistry
Professor (with tenure)	58 min	13	Chemistry
Medical biotechnology			
Group Leader	1 h,23 min	6	Biotechnology
Project Leader	58 min	4	Biotechnology
Project Leader	1 h, 4 min	2	Biotechnology
Group Leader	1 h 39 min	6	Biotechnology
Group Leader	1 h 59 min	12	Microbiology
Professor (with tenure)	1 h, 4 min	12	Chemical engineering
Project Leader	1 h, 54 min	4	Biotechnology
CSO	47 min	15	Biochemistry
Project Leader	1 h, 48 min	12	Chemistry
Group Leader	1 h, 10 min	13	Microbiology
Group Leader	1 h, 58 min	6	Microbiology
Professor (with tenure)	1 h, 7 min	4	General engineering
Industrial biotechnology & medical Biotechnology			
Principle Scientist	1 h, 18 min	5	Biotechnology
CEO	32 min	10	Chemistry
CTO	1 h 27 min	5	Biotechnology
CSO	1 h, 25 min	6	Biotechnology
Professor (with tenure)	48 min	4	Microbiology

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