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Distance beyond Spatial Separation: Interfaces of Process Development in Biotechnology

Michael Raven
Technical University Berlin / ESMT European School of Management and Technology
Technology and Innovation Management
michael.raven@esmt.org

Abstract

To guarantee an efficient transition from invention to market for new products, many different managerial as well as technical perspectives must be considered. Process development links the invention with the production scale. Thereby, process developers have to incorporate information across various interfaces. By means of an effect analysis we investigate the influencing factors at the interfaces of process development in biotechnology. Based on 31 in-depth cases a model of the interfaces is proposed which distinguishes the distance between the involved parties and the inherent characteristics of the interfaces. Different categories of distance as well as different types of inherent factors are ranked according to their relevance. As essential dimensions of distance we identify relational distance, different incentive systems, distance of educational background, and different mindsets. Although geographical distance is often used as indicator for overall distance, the data points out that geographical distance is neither particularly important for the success of transitions at the interfaces nor does it highly correlate with other dimensions of distance.

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To guarantee an efficient transition from invention to market for new products, many different managerial as well as technical perspectives must be considered. Process development links the invention with the production scale. Thereby, process developers have to incorporate information across various interfaces. By means of an effect analysis we investigate the influencing factors at the interfaces of process development in biotechnology. Based on 31 in-depth cases a model of the interfaces is proposed which distinguishes the distance between the involved parties and the inherent characteristics of the interfaces. Different categories of distance as well as different types of inherent factors are ranked according to their relevance. As essential dimensions of distance we identify relational distance, different incentive systems, distance of educational background, and different mindsets. Although geographical distance is often used as indicator for overall distance, the data points out that geographical distance is neither particularly important for the success of transitions at the interfaces nor does it highly correlate with other dimensions of distance.

1. INTRODUCTION

Process development is the connector between invention and manufacturing. Transitions from and to process development are complex and critical development stages on the way to successful market launch of new products. Poor coordination of process development interfaces can lead to time delay and costly rework in new product development (NPD). Despite its relevance there is no research yet which conceptually characterizes the interfaces of process development (Kurkkio, Frishammar, & Lichtenthaler, 2011).

Process development has to unite requirements from the market side, production constraints from the supply side, and product characteristics from the research side. In addition, regulatory authorities and business strategy affect process development. This results in various heterogeneous interfaces in a dynamic environment. The combination of interdisciplinary tasks and long development cycles in biotechnology also promote collaborations, which result in external interfaces (Dahlander & Mckelvey, 2005; Jungbauer & Göbel, 2012). These external interfaces are implemented on a supra-regional scale and are crucial to guarantee state-of-the-art developments (Zeller, 2001). The biotechnology industry is highly dependent on patent protections which also foster the creation of networks (Blind, Edler, Frietsch, & Schmoch, 2006). The examination of process development interfaces is complicated due to the ill-defined boundaries with regard to content in contrast to the strict cutoff points between organizational units.

Many previous studies have examined the organizational units of NPD (Krishnan & Gupta, 2001). Pisano (1997) has established the framework of the "development factory" which distinguishes process development from product development and production. On the one hand, product development results in patents or prototypes and corresponds to the invention or discovery of potential new products. On the other hand, process development implements a production strategy in order to realize the market launch of a new product. The "development factory" already highlights the two most fundamental interfaces of process development: Firstly, the intersection between product and process development; secondly, the intersection between process development and production. However, we cannot assume that these interfaces are associated with equal organizational departments. In contrast, we emphasize that the relation between the involved parties can be very heterogeneous. For example, an interface can be external across the globe with very different organizational settings or internal within the same building and very close personal ties.

The objective of the current paper is to identify and classify such organizational structures, interdependencies, and socio-psychological aspects which influence the interfaces of process development. With other words, which mechanisms influence the quality of the process development interfaces to which degree? Through an in-depth analysis of the influencing factors contingencies at the interfaces are enlightened. In particular, the notion of distance between the protagonists is further refined. Therefore, our analysis enables a more complete understanding of efficient interface management.

2. THEORETICAL BACKGROUND

In analogy to many research efforts in NPD in the past, the theoretical foundation for our analysis draws on the findings of contingency theory (Brown & Eisenhardt, 1995). Contingency theory postulates that the strategy of an organization must align internal characteristics with requirements from the environment (Scott, 1981, p. 89). This alignment can be achieved on two levels (Lawrence & Lorsch, 1967):

1. The structure of the subunits fits the environment.
2. The mode of integration fits the organizational characteristics.

Distance or proximity respectively in this context and in particular its influence on the integration mode and the structure of the subunits has not been researched in the past. Thereby, the current paper elaborates on the concept of distance which is also valuable to other management fields (Nachum & Zaheer, 2005). As such, it contributes to a more complete model of distance (Ambos & Ambos, 2009).

For our analysis we develop a two-dimensional theoretical framework which serves as orientation for a holistic examination of the interfaces. We differentiate between distance and inherent factors (see fig. 1).

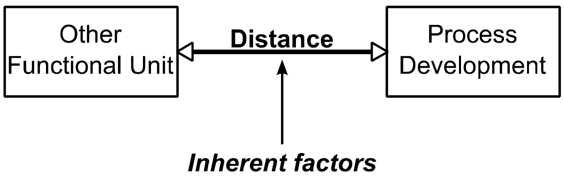

Figure 1 | Exemplary interface of process development

2.1. Distance

Distance between individuals, between regions, or between organizational units has been described as a multidimensional phenomenon in the past (Boschma, 2005). The term ‘distance’ is mainly used interchangeable with the term ‘proximity’.

A unidimensional treatment of distance as spatial separation has been criticized in the literature (Carrincazeaux, Lung, & Vicente, 2008). However, geographical distance is the most intuitive form of distance and is most widely used when referring to “distance” in the literature. Torre & Rallet (2005) show that geographical distance can even be further distinguished into travel time, travel cost, absolute and perceived spatial distance.

One of the first and most meaningful expansions was the introduction of organizational distance between two firms (Rallet & Torre, 1999; Torre & Gilly, 2000). Especially Rallet & Torre (1999) emphasize that organizational proximity is much more important for successful collaborations than geographical proximity. Organizational distance addresses the firm level as unit of analysis which is much more difficult to operationalize in comparison to the geographic distance. Organizational distance can mean that incentive systems or administrative structures across the interface show great variability. In addition, different financial budgets as well as different firm or department cultures can lead to greater organizational distance.

Boschma (2005) has added the concept of institutional and individual distance to the taxonomy. Institutional distance relates to a macro-perspective and contains the general “rules-of-the-game” (Boschma, 2005). This means that foreign languages and the locus of interaction add to the overall distance between two functional units. Locus of interaction refers to the general set-up of the interface, i.e. a transition between different legal entities versus a transition within the same entity and with similar legal environments. In contrast to the institutional distance, the concept of individual distance can be defined as the socially embedded relationship between actors at the micro-level (Boschma, 2005). Thereby, individual distance must distinguish between length and profoundness of the relationship, e.g. a personal contact can exist for a long time, but this does not necessarily imply a trustworthy relationship and vice versa.

In 2006 a first meta-analysis of the distance/proximity concept has been published by Knoben & Oerlemans (2006). Besides the already mentioned dimensions, they augment the concept with cultural distance and technological distance as influencing factors. Although the authors point out in their meta-analysis that institutional and cultural distance across national borders overlap, we want to analyze the two dimensions separately in order to account for the mostly globalized development activities in biotechnology. Technological distance, on the one hand, refers to hard facts, such as similar technical equipment, on the other hand, it also includes more soft facts, such as a common knowledge base and technical comprehension (Boschma, 2005). Therefore, we operationalize technological distance in terms of technical equipment, educational background, scientific language, and working method/mindset. The latter refers to distance which arises due to different point of views on specific problems, e.g. a scientific, economical, or opportunistic approach to problem solving.

Certain problems emerge with regard to the constitution of the distance taxonomy. Following Knoben & Oerlemans (2006) three main issues can be pointed out:

- Assignment of different labels to identical dimensions of distance
- Overlapping of dimensions of distance
- Different interpretation of identical labels for dimensions of distance

Furthermore, Knoben & Oerlemans (2006) indicate that the dimensions of distance are specific to the research subject. Therefore, we also align our dimensions with Zeller (2002, 2004) who has researched inter and intra-organizational project teams in biotechnology. In conclusion, spatial, organizational, institutional, individual, cultural, and technological distance are identified as the six subcategories for our analysis (see tab. 1).

Table 1 | Different dimensions of distance

Geographic distance	**Organizational distance**	**Institutional distance**	**Individual distance**	**Cultural distance**	**Technological distance**
• Travel time • Travel cost • Absolute distance • Perceived distance	• Incentive system • Administrative structure • Firm/depart. culture	• Macro-perspective • Locus of interaction • Foreign language	• Micro perspective • Length of relationship • Profoundness of relationship	• Indices of national cultures	• Working equipment • Scien. language • Educational background • Mindset
Torre & Rallet, 2005	Rallet & Torre, 1999; Torre & Gilly, 2000	Boschma, 2005	Boschma, 2005	Knoben & Oerlemans, 2006	Boschma, 2005; Knoben & Oerlemans, 2006

Based on this overview the different dimensions of distance are classified and rated with regard to interface management in process development. Proposition 1 concludes the first step of the analysis.

Proposition 1: *A refined assessment of the notion of distance as well as an understanding of its implications is a prerequisite for efficient interface management.*

2.2. Inherent Factors

The second part of our theoretical framework addresses inherent factors, which can be positive or negative moderators to the concept of distance. The most important factor for the distance between two agents is the extensively researched flow of information (Allen & Cohen, 1969). Closely linked to information flow is the transfer of knowledge, which is particularly important in high technologies such as biotechnology (Deeds & Decarolis, 1999). The form of documentation as well as the degree of standardization are crucial characteristics for the information flow at the interface (Blind & Gauch, 2009), e.g. “Standard Operating Procedures” (SOPs) control when and in which form functional units communicate. A precondition for the successful transition of information is the absorptive capacity of the receiving agent (Cohen & Levinthal, 1990). Adler (1995) has been the first to emphasize the coordination mechanism between product development and process development as crucial success factor in NPD. The efficiency of coordination mechanisms also correlates with the coordination costs (Cummings & Kiesler, 2007), which can be ascribed to transaction cost theory. Malerba & Orsenigo (2000) refer to experience of the agents as well as the technical nature of the new product as success factors. In the light of distance due to different incentive systems, we also include the willingness to cooperate at the interface into our set of inherent factors. For example, the willingness to cooperate can largely vary depending on the perceived appreciation from the other side of the interface. Table 2 summarizes the inherent factors of an interface.

Table 2 | Summary of inherent factors

Information flow	**Coordination mechanism**	**Willingness / Awareness**	**Technical complexity**	**Experience**
• Knowledge • Documentation • Standardization	• Transaction costs	• Perceived appreciation from other side	• Sophisticated product / process	• Technical • Interpersonal
Allen & S. Cohen, 1969; Deeds & Decarolis, 1999	Adler, 1995; Cummings & Kiesler, 2007	Gupta et al., 1986; Ettlie, 1995	Malerba & Orsenigo, 2000	Malerba & Orsenigo, 2000

In conclusion, many contingencies affect the successful transition at the interfaces of process development. We can distinguish hard facts, such as different technical working equipment or spatial distance, from more soft facts, such as willingness to cooperate. In particular, soft facts are prone to subjective perceptions, but might be easier to govern. Furthermore, we can differentiate between dimensions/factors at the micro level and at the macro level. In the following analysis we provide a detailed assessment of the different aspects**.**

Proposition 2: *Interfaces of process development comprise of decisive inherent factors, which indirectly or directly determine the success of a transition at the interfaces.*

3. METHODS

3.1. BIOTECHNOLOGY

Biotechnology is a progressive industry where many different disciplines, technologies and skills have to be combined to develop new products (Gillis, 2003). For instance, the beginning of product development is defined by natural scientific work and gradually shifts to an engineering perspective along process development although a clear cut cannot be determined. Protagonists in biotechnology, individuals as well as companies, have very heterogeneous backgrounds in terms of educational background, firm history and overall mindset. For example, on the one hand, pharmaceutical companies, such as Sanofi S.A., have recently shifted towards biotechnology from the traditional chemical engineering side. On the other hand, companies, such as Boehringer-Ingelheim AG & Co.KG, entered the biotechnology industry from the biological side and have been involved in biotechnology for over 100 years. In addition, over the last two decades many small companies, often university spin-offs, have entered the biotechnology industry (Murray, 2004; Zucker, Darby, & Armstrong, 2002). This results in different firm cultures as well as different problem perceptions. In the light of these conditions, it comes as no surprise that NPD in biotechnology is characterized by various interfaces and hurdles among heterogeneous partners within the same organization and across organizational boundaries (Bianchi, Cavaliere, Chiaroni, Frattini, & Chiesa, 2011). Last but not least, NPD projects in biotechnology are time critical and costly, Therefore, efficient interfaces are crucial for overall success (Pisano, 2010). In summary, this makes the biotechnology industry a particular convenient example for the purpose of our analysis.

Powell, Koput, & Smith-Doerr (1996) point out the interdependences between a complex knowledge base and a dense network of interacting partners in biotechnology. Due to the dense network an integration problem emerges because knowledge and competences have to be integrated across interfaces into the functional units. The integration process is further complicated as boundaries and interfaces are ill-defined in high-technology industries such as biotechnology and development activities often rely on implicit knowledge which also impedes a modular structure of NPD (Pisano, 2010).

One future development which emphasizes the importance of interfaces in biotechnology is the implementation of *Quality by Design* (QbD). QbD is a set of development principles which are recommended in medical biotechnology by the regulatory authorities but can also be partially found in industrial biotechnology. QbD requires stronger coordination and more extensive knowledge transfer between functional units than previous development strategies.

Isolated optimization of single development activities is not useful according to QbD principles. A holistic understanding of process development across boundaries is the precondition for effective introduction of QbD (Rathore & Winkle, 2009). Thus, iterative exchanges are needed and at the same time the demands concerning the interfaces are increased.

Although biotechnology is a worthwhile example for our analysis, the mentioned properties are not unique to biotechnology and are also found in other industries. For example, the textile sector needs to combine the creativity of designers with strict engineering competences on a global scale in order to successfully develop new products. Otherwise, friction losses at the interfaces possibly compromise the efficiency of NPD. Within our analysis we differentiated between medical and industrial biotechnology but no significant differences with regard to the design of the interfaces can be observed. This supports the argument that the findings of this study are also transferable to other industries with similar characteristics.

3.2. Data Collection and Analysis

On the one hand, the current paper relies on explorative investigations in order to identify the interfaces of process development and in order to explain and interpret the interrelations of the dimensions/factors. On the other hand, the paper builds on theoretically developed frameworks as presented in the previous section. In order to fulfill the requirements of such a study, we have to rely on a combination of methods. Therefore, the interview guideline for our semi-structured interviews, which is the core of our analysis, is split into two main parts: The first part mostly contains open ended questions concerned with the general setting of process development as well as the meaning of the interfaces. The second part of the interview guideline then leads to quantitative questions which are aligned with the predefined dimensions of distance and inherent factors. This means the first part of the interviews intentionally allows for open minded unbiased discussions, while the aim of the second part is to collect data based on Likert-type scales with 5 categories. With respect to the latter the respondents were asked to remember the last NPD project for which they experienced a transition to or from process development.

In summary, the empirical foundation for the analysis consists of 31 semi-structured in-depth interviews as well as secondary data, such as regulatory guidance and best practice reports. With regard to the interviews, approximately 40 hours of recorded data were transcribed, coded, and investigated. Initial contacts were identified based on suggestions of a local university chair for bioprocess development. Successively, further interview partners were approached based on personal recommendations of previous respondents. Complementary, experts were identified and asked for follow-up interviews at bioproduction conferences. In accordance with Eisenhardt (1989) and Glaser & Strauss (1967) experts were contacted until theoretical saturation was reached. The data set has also been used by Raven (2013).

To some extent our research design builds on the techniques of grounded theory which allows for a systematic approach of theory building (Glaser & Strauss, 1967). However, the practical implementation of grounded theory is controversially discussed (Kelle, 2005). In line with the methodology of grounded theory, we have conducted unstructured interviews beforehand which served as a basis for the interview guideline as well as for a rudimentary coding scheme. Based on the first 20 percent of the semi-structured interviews the coding scheme was then gradually refined in the light of the new insights from the interviews. However, we also used the theoretical considerations from the previous section in order to structure the quantitative questions. Therefore, the overall analysis depends on a mixed method which combines deductive and inductive reasoning along the research process. As an advantage of the proposed mixed method, new hypotheses can be created and tested within the same analysis (Creswell, 2002; Tashakkori & Teddlie, 2002). On the downside, the research design requires exceptionally time-consuming data collection and data evaluation requires high contextual understanding.

Out of the 31 semi-structured interviews, 26 respondents participated in the quantitative analysis. Within this part, interviewees were asked to report the importance as well as the realization of influencing factors for a particular interface, i.e. mainly the transition from product development to process development.

Overall, the aim of the paper is to assess the process development interfaces on the basis of an effect analysis. This means that the data is investigated in view of three general criteria (Stamatis, 2003):

1. How frequently does a factor influence a particular interface?
2. How important is this influence for the interface?
3. How long takes recognition and how difficult is troubleshooting of a problem due to a particular influence?

3.3. Sample Description

The data sample of our analysis covers a broad range of relevant characteristics. First and most important, the respondents are responsible for different fields of activities around process development. This implies that the data provides various perspectives and prevents a one-sided account of a particular interface, although the main focus lies on the interface between product and process development.

In order to account for size effects, the sample also includes varying firm sizes. In table A.1 the size of the interviewed companies is categorized according to the recommendations of the European Commission[1]. Due to the aforementioned relevance of academia in biotechnology, five in-depth interviews were conducted with biotechnology professors which had exten-

[1] European Commission (2003). Recommendation 2003/361/EC: SME Definition. Retrieved Nov. 28, 2012.

sive experience with interfaces to industry. Furthermore, the sample represents different hierarchy levels, educational backgrounds, and levels of experience. With regard to hierarchy levels, positions range from project leaders up to management board. All respondents hold at least one university degree, but very heterogeneous fields of study within the areas of natural science and engineering are contained in the sample. Each interviewee is affiliated for at least two years with the corresponding organization. Out of 31 cases 24 relate to a German-speaking work environment, including Austria and Switzerland. However, the remaining 7 cases refer to Canada, Great Britain, Mexico, the Netherlands, or the United States and confirm that the findings don’t contain a regional bias. One foreign respondent indicated that in a German-speaking work environment process development receives higher appreciation by the general management. Therefore, we argue that the findings are conservative results. Overall, respondents showed great interest in the research topic and were open minded about their perceptions although many insisted on being granted with anonymity.

4. RESULTS

Complete understanding of the factors influencing the interfaces of process development is a crucial precondition for the success of NPD projects. With regard to the technical literature, there are best practice reports on the implementation of QbD-principles in the development process (CMC Biotech Working Group, 2009). However, the technical literature doesn’t account for the design of process development interfaces, especially with regard to organizational aspects, although organizational and technical aspects are very much intertwined. The following three subsections investigate the interfaces by combining aspects from the technical literature and from the management literature.

4.1. Interfaces of Process Development

Many stakeholders rely on the functional unit of process development. Therefore, process development is also sometimes referred to as bridge or hub within the innovation process. The three main functional units interacting with process development are: product development, production, and marketing & sales (see fig. 2). Remarkably is the integration of engineering, natural science, and commercial perspectives within the unit of process development. Process developers have to design a manufacturing solution which obeys the equipment constraints at the production site but at the same time meets the commercial demands, such as prospective pricing and required quality attributes.

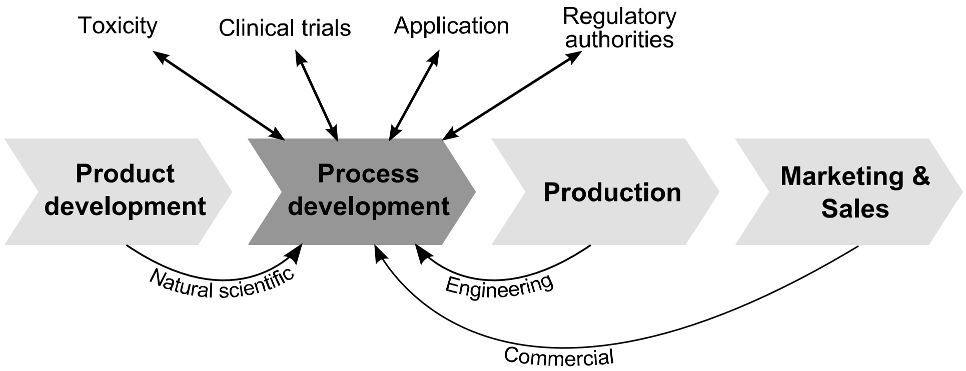

Figure 2 | Overview of interfaces

Dependent on the business model, further stakeholders form interfaces with process development. For instance, in early development stages process development has to provide small amounts of the prospective product for the assessment of environmental and health risks in toxicity tests. Furthermore, in medical biotechnology process development needs to make material available for clinical trials which have to prove the effectiveness of the potential treatment. In analogy to clinical trials, industrial biotechnology companies conduct application tests to prove the desired functionality of the future product. In medical biotechnology but partially also in industrial biotechnology the complete manufacturing process needs to be certified and documented before a new product can be launched in the market. A great challenge along process development is to always provide the exact same product characteristics across different production scales, otherwise clinical trials and application tests might become worthless. Scalability is particularly difficult as production in biotechnology relies on heterogeneous living cells. The multi-sided nature of process development is also confirmed in the interviews:

> *”Process development is the center and has to please everyone: Characteristics of the cell lines must be preserved, the process must enable low manufacturing costs, must be robust, easily transferable to different production facilities, and well documented in order to serve all stakeholders.”*

The interfaces of process development are characterized by varying organizational forms. With regard to the interface between product development and process development, in-house interfaces between two departments are predominant. The second most diffused interfaces are alliances and contract development. The cases have shown that contract development is particularly beneficial for small companies in order to quickly generate first cash-flows and gain market understanding.

Although product development, process development, production, and marketing & sales are almost always assigned to self-contained departments, this doesn’t imply that the departments are of equal size or receive similar attention by the management board. As a matter of fact, process development is usually a smaller department relative to product development and production. From this follows that process developers commonly complained about little appreciation.

> *“I think process developers are the crucial link, but from the overall perspective, they neither have the image of the innovator, which is in product development/drug discovery, nor have the*

fame of being responsible for the actual value creation, which is in production. In comparison to the other units we are not equally appreciated."

4.2. DISTANCE

All respondents have confirmed that the quality of interfaces and thereby the likelihood of a successful transition from one functional unit to another depends on the distance between the involved parties. Distance in this context must be understood as a multidimensional construct beyond spatial separation of particular departments. Notable is that we cannot draw the conclusion that more proximity or less distance respectively will always benefit the quality of the interfaces because too much proximity can also limit openness and flexibility (Boschma, 2005).

In the following, the different dimensions of distance and their importance for successful transitions are assessed on the basis of the qualitative discussions. In addition, respondents have rated distance[2] and relevance[3] for the last transition which they experienced. We sort the dimensions of distance in three categories of relevance: essential dimensions, awareness dimensions, and subordinate dimensions.

Essential dimensions. First of all, distance of personal relationships, distance of incentive systems, and distance of educational backgrounds are rated as the most important dimensions of distance by the respondents. On a scale from 1 to 5 the interviewees rated the relevance of these three factors on average with 4.26, 3.70 and 3.63 respectively. The distance between working methods or mindsets reveals the largest distance between two functional units. Therefore, we denote these four factors as *essential dimensions* of distance.

[2] On a scale from 1 to 5 where 5 indicates "very large distance" and 1 indicates "no distance".
[3] On a scale from 1 to 5 where 5 indicates "utmost importance" and 1 indicates "no importance".

With a mean of 4.26, distance of personal relationships, which is also referred to as relational distance, is the only factor which denotes between ”important” and ”utmost important” and therefore, is the most influential factor of all distance dimensions.

The respondents also reported the overall success[4] of the last transition which they experienced. In our analysis we use this measurement as dependent variable. Assuming the interval between the 5 categories of the dependent as well as of the independent variable are equal, a ordinary least square regression shows that the relational distance is correlated with the success of the transition at the 10 percent significance level ($p = 0.073$, $\beta = -0.47$), i.e. a smaller distance between personal contacts improves the likelihood of success at the interface.

Relational distance can be differentiated into length of personal contact and quality of personal contact. According to the cases, length of personal contact is especially beneficial when well-established and quick team work is required. However, sympathy between the involved parties serves as a prerequisite for the beneficial effect of personal contact.

> *”We know each other extremely well but we argue a lot. [...] I think you don’t have to know each other for a long time but rather need to feel sympathetic toward each other.”*

The beneficial impact of close personal contacts can be ascribed to its interaction with other influencing factors: Close relationships enable informal flow of information, they help to overcome different incentive schemes, and influences of locus of innovation across firm boundaries, cultural differences, as well as language barriers. The quality of the personal contact is not completely exogenous as organizational measures can foster personal relationships, but organizational measures must be carefully chosen as well-intentioned arrangements can also turn out to be counterproductive.

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[4] On a scale from 1 to 5 where 5 indicates ”utmost success” and 1 indicates ”no success”.

"There are many reasons for problems: first of all, fast job-rotations within the company. If you have conducted one or two projects with the same contact person and then the contact person changes, you have to start over again to establish an efficient teamwork."

The second most important dimension of distance according to the respondents is the incentive system. Incentive systems relate to the compensation schemes of individuals but also account for the objectives at the department or firm level. For example, the transition from product to process development is impeded if product developers are compensated on the basis of different success factors than process developers. The challenge for top management is to align objectives and priorities not only within one department but across all boundaries. This becomes particularly difficult if incentives must be aligned with external institutions. Consistently, there are high interdependencies between the quality of the coordination mechanisms and the distance in the incentive systems.

"A perfect example is my former employer: Researchers are paid according the number of new products at the market, in contrast, process developers are paid according to profitability of new products. This creates problems."

Educational background is the third *essential dimension* which can lead to distance at the interfaces. We distinguish between distance due to different educational disciplines, i.e. a natural scientific background compared to an engineering background, and distance due to different levels of education, i.e. an academic employee compared to a blue-collar worker. Process development in biotechnology is particularly confronted with varying educational disciplines (see fig. 2), but also the latter aspect is a particular risk for the interfaces in biotechnology. At the front end, process developers mainly deal with researches holding a PhD, but simply due to the size of the operational equipment more and more workers are needed for further scale-up of the process. Educational background is also linked to the fourth essential dimension of distance, namely distance in working methods and mindsets.

Dependent on educational background, perception of problems and approaches to problem-solving vary.

”With my expertise, I would use biomolecular methods in order to produce the protein more efficiently. A chemical engineer, who is more on the purification side, would say: ’I cannot change the protein, but I can use a membrane filtration technique which shifts the equilibrium.”

Besides the educational background, the age of the employees is a determinant for the preferred working methods and the mindset. Aforementioned progression in biotechnology leads to great variance in the individual body of acquired knowledge dependent on the age, i.e. methods and approaches which were standard 10 years ago have become irrelevant today (Wagemann & Sell, 2010).

“People, who are responsible in the pharmaceutical industry today, have learned for one generation to test into compliance, [...]. Now the same people are supposed to implement knowledge and information management and are advised to define degrees of freedom. That is not possible with the current mindset. There has to be a mentality-change.”

In contrast to relational distance and incentive systems, the effect of distance due to different educational backgrounds and different working methods on the success of transitions is ambiguous. On the one hand, large distance in educational backgrounds and working methods without means of communication lead to substantial problems, such as time delays. On the other hand, the combination of interdisciplinary competences is a precondition for successful problem-solving in biotechnology. The management challenge is to enable the exchange between different disciplines without limiting the synergies within the same discipline. Figure 3 and 4 illustrate that too much as well as too little distance decreases the likelihood of a successful transition at the interfaces.

”That is a major challenge for the organization. How to organize project meetings, how to design the cafeteria, in order to have both directions of communication, i.e. on the one hand, within one discipline to enable the exchange of scientific knowledge and on the other hand, across different disciplines to avoid isolated development of only one discipline.”

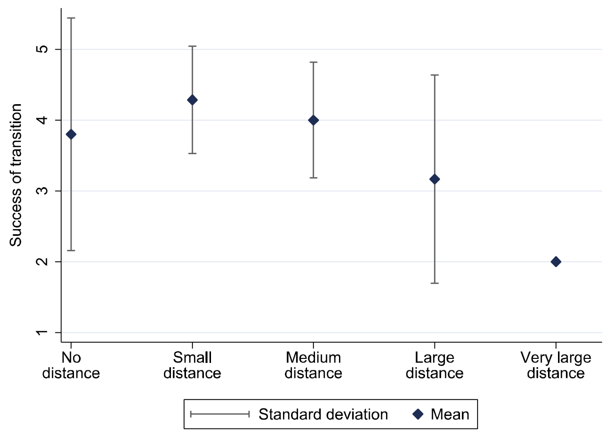

Figure 3 | Distance of educational background

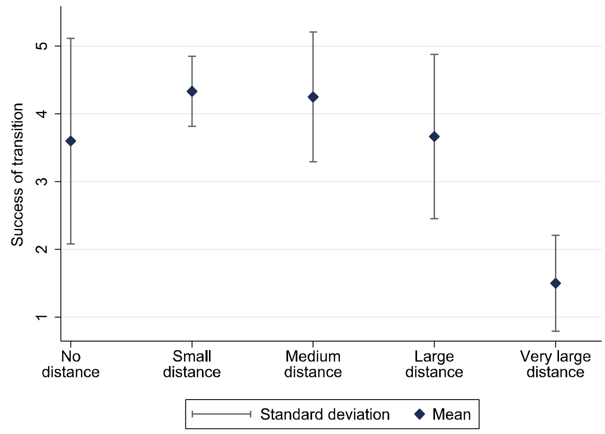

Figure 4 | Distance of working methods/mindsets

Awareness dimensions. The second level of distance dimensions are not rated as important as the *essential dimensions.* Respondents reported a mean between 3.44 and 3.26 with regard to relevance for cultural background, organizational structure, firm culture, and scientific language. These factors can become crucial if they are not properly considered in the design of the interfaces. This means, the relevance of the four factors highly depends on the specification of the willingness and awareness as inherent factors of the interface. Therefore, we denote these four factors as *awareness dimensions*. Distance of cultural background significantly correlates with the success of transitions at the interfaces ($p = 0.025$, $\beta = -0.38$). For the other three dimensions the coefficients point in the intuitive direction but the correlations are statistically not significant.

Interfaces of process development are increasingly confronted with transitions across firm boundaries and country’s frontiers due to the growing relevance of networks. This emphasizes the importance of *awareness dimensions* in the future. In particular, different cultural backgrounds, different organizational structures, and different firm or department cultures must be considered in this line of thinking. Different foreign languages are also related to these forms of boundaries but play only a subordinate role according to the respondents, i.e. mean equal to 3.04 with regard to relevance.

Organizational structure and firm/department culture are also affected by the firm size. Firm size relates to financial capabilities but similar to foreign languages this has only a minor effect on the interfaces, i.e. mean equal to 2.11 with regard to relevance. Interviewees denoted the emergence of high bureaucratic hurdles as the major threat with regard to high distance between organizational structure, firm culture, or financial capability.

> *"When small and medium sized companies cooperate, the transition is much more straightforward compared to collaborations between large and small companies, then it is a much more formal interface."*

Subordinate dimensions. The third and last level of distance dimensions are *subordinate dimensions*, namely geographical distance, locus of interaction, foreign languages, and financial capabilities. The mean with regard to relevance ranges from 3.04 to 2.11 and for all four factors no statistical effect on the success of the transition can be reported. Although geographical distance is the most intuitive form of distance, it is remarkable that the cases reveal a low relevance of geographical distance and no significant effect on the success of the transition. According to the cases, the capabilities of modern telecommunication facilities must be held responsible for this result. With regard to cost efficiency at the transition and with regard to the quality of the personal contact geographical distance can have an influence but it is not a main driver of overall distance.

One might argue that geographical distance is not the driver of overall distance but strongly correlates with the more important dimensions. However, this hypothesis is not supported by the data. Assuming interval scales, table 3 points out the correlations between geographical distance, *essential dimensions*, and *awareness dimensions*, but geographic distance is not particularly strongly correlated to any other variable, with the highest correlation to relational distance (ρ = 0.41). As already indicated, the strongest correlation exists between Mindset and Educational distance.

Table 3 | Pairwise correlation of different dimensions of distance

Variables	Geo-graphic	Rela-tional	Incen-tives	Educa-tional	Mindset	Cultural	Organi-zation	Firm culture	Scient. langu.
Geographic	1.00								
Relational	0.41	1.00							
Incentives	0.26	0.39	1.00						
Educational	-0.14	0.26	0.25	1.00					
Mindset	-0.34	0.05	-0.05	0.68	1.00				
Cultural	0.30	0.65	0.06	0.14	0.32	1.00			
Organization	0.20	0.48	0.31	0.32	-0.01	0.37	1.00		
Firm culture	0.22	0.44	0.17	0.32	0.35	0.68	0.44	1.00	
Scient. langu.	0.08	0.08	0.29	0.32	-0.01	-0.14	0.20	0.27	1.00

Noteworthy is that geographic distance is the only variable where relevance depends on the actual realization of distance. Figure 5 shows that for transitions with practically no spatial distance this aspect was of high importance, but as soon as a small geographical distance exists the importance of the factor is substantially reduced. In line with the studies of Allen (1984) the following quote supports the finding that distance of a couple of meters can be beneficial, but larger distances don't have significant effects for the process development interfaces.

> *"If I cooperate with somebody who is not farther away than 100 meters, then it is extremely easy. If he is 500 meters away, then it is exactly the same as with 1,000 kilometers."*

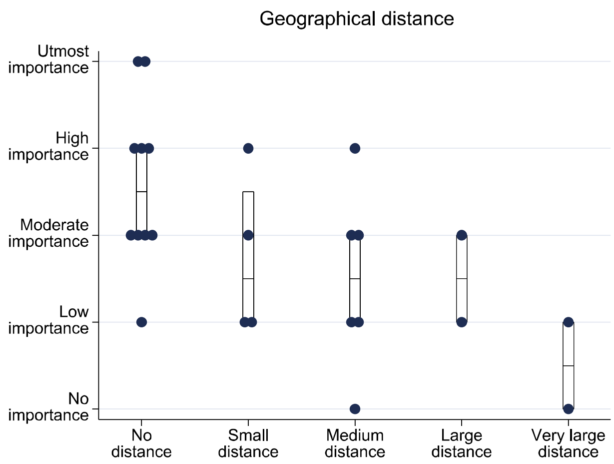

Figure 5 | Relevance of geographic distance on the geographic distance

Two aspects of the aforementioned technological distance are differences in physical volume and differences in the technical equipment. The respondents confirmed that interfaces have to overcome large distance with regard to these two aspects, but due to the tasks of process development these differences are perceived as natural elements of the interfaces. Interviewees referred to it as an "almost tautological question".

Nevertheless, there are still substantial problems associated to distance with regard to volume and equipment. In addition, they are also not exogenously given factors. In contrast, more efficient production processes with higher titers lower the required volume in the final scale and thus relieve the friction between the large volumes in production and the very small volumes in the laboratories. Furthermore, the technical equipment can be aligned as much as possible, especially in the field of analytics, i.e. measurement methods, where the usage of consistent technologies is crucial.

"The technical equipment has to be different, if you want to scale-up the process. [...] We try to keep the development stages as similar as possible, but it is never possible to entirely represent a 10 m^3 scale in a 2 liter volume. For example, the pressure ratio is completely different and cannot be transferred 100 percent. We try to align the measuring techniques. Thereby, we try to compensate for the scale differences."

4.3. Inherent Factors

Inherent factors directly as well as indirectly affect the quality of interfaces in process development. In analogy to the dimensions of distance, interviewees rated the relevance of inherent factors on a Likert-type scale with 5 items. Based on the relevance, we distinguish between three categories: *fundamental factors, ambivalent factors, secondary factors.*

Fundamental factors. Information flow (mean = 4.86), willingness/awareness (mean = 4.64), as well as data handling (mean = 4.36) are the most important inherent factors for the interfaces of process development. Therefore, they are denoted as *fundamental factors*. All three factors are significantly correlated to the success of the transitions at the interfaces at the 10 percent significance level (information flow: $p = 0.047$, $\beta = -0.61$; willingness/awareness: $p = 0.002$, $\beta = -0.58$; data handling: $p = 0.053$, $\beta = -0.65$).

Especially information flow takes on a special position as many other factors directly or indirectly relate to this factor. The information flow can be further differentiated into informal and formal flow of information where formal flow of information is closely linked to data handling. Within data handling we can distinguish between data preparation, on the one hand, for external stakeholders such as regulatory authorities and patent offices, and on the other hand, for project-oriented purposes. Notable with regard to data handling is the comparably low degree of standardization at the interface between product development and process development. The degree of standardization can be determined by two criteria: the data medium and the time of documentation.

With regard to the data medium, most of the data transfers in the beginning of process development still rely on unstructured documents and informal e-mails. This lag of structure impedes automation and standardization at the interfaces of the front end of process development. In comparison, the interface between process development and production is much more standardized. This interface usually relies on standardized data tools, such as SAP, in order to transfer information.

In relation to time of documentation, a prompt documentation of new findings is often disregarded, but prompt or even real-time documentation is a precondition for continuous risk management and efficient problem-solving across functional boundaries.

Informal information flow is particularly important at the interface between product development and process development. The nature of this interface requires a forward-looking and creative work environment. At this stage a direct and straightforward exchange is absolutely crucial.

> *“I call this ’coffee engineering’. I have always done it that way: regularly coffee breaks in the right social environment where people can effectively exchange their knowledge. [...] If somebody starts to cut down on coffee machines, this would be tremendously counterproductive.”*

Furthermore, the flow of information must be analyzed with regard to the quality of the passing information. By no means, the transition at the interfaces can always be improved by transferring more data. This just leads to more data graveyards. Instead, the differences between data, information, and knowledge must be carefully considered. Only structured data can provide new information and then eventually create new knowledge. For efficient transitions at the interfaces it is critical that information is filtered according to the specific situation.

> *”Information must be incorporated in data systems where it can be retrieved again. [...] The main challenge is that information goes in but never comes out again.”*

In addition, an efficient design of the information flow at the interfaces depends on a detailed understanding of the sender recipient relationship. The transmitted information is only valuable as long as the recipient has the competence, absorptive capacity, to process the information.

At the interfaces of process development, both sides usually operate as sender and recipient at the same time. For example, product development needs to provide process development with sufficient information to enable an optimal starting position for the development of the manufacturing process. At the same time, process development has to pass on boundary conditions and requirements with respect to production facilities which constrain the scope for development. Particularly challenging are the changing constraints over time as they are very probable in the long development times of biotechnology.

Conducive enabling and constraining is based on the willingness to relate to the respectively other side. This doesn’t imply complete understanding of each step but general awareness for the development problems and methods of the cooperating partner. In the previous section we already pointed out several distance factors which are decisive for the success of transitions if a certain level of awareness is not fulfilled. In the light of this finding, figure 6 indicates that awareness should be regarded as a hygiene factor as defined by Herzberg, Mausner, & Snyderman (1959). This means without a certain level of awareness the likelihood of success is drastically decreased but as long as a high level of awareness is fulfilled the difference between ”high” and ”very high” levels of awareness is small.

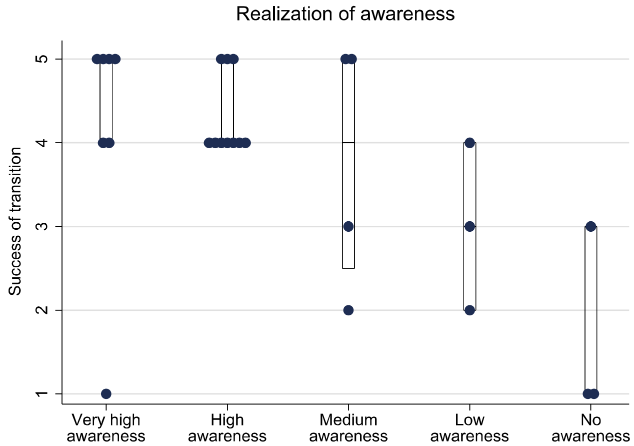

Figure 6 | Success of transition dependent on the level of awareness for the interfaces

Ambivalent factors. Experience with the interfaces and coordination methods are rated between "high" and "moderate" importance, both are assigned a mean of 3.6 with regard to relevance. The two factors stand out because they can affect the interfaces either in a positive or negative direction. Therefore, they are denoted ambivalent factors. If a certain sequence of activities is performed on a routine basis, work experience is beneficial for an efficient organization of transitions because different objectives and technical capabilities are already appreciated. Therefore, it comes as no surprise that awareness is partially correlated to experience with ρ equal to 0.43 (see tab. 4). In contrast, experience impairs the interfaces of process development if it leads to gridlocked structures.

"I have really experienced that process developers said: 'We have always done it like this. We always operate at 118 degree Celsius for 120 minutes.' For the product at question, it was completely wrong and destroyed most of it, but they didn't even care."

"Sometimes it can be very tedious, if people believe they know it all. They aren't willing to change their preconceived opinions. Then it is more stressful to work with experienced staff than with inexperienced."

Table 4 | Pairwise correlation of inherent factors at the interfaces

Variables	Information	Awareness	Data handling	Experience	Coordination
Information	1.00				
Awareness	0.36	1.00			
Data handling	0.24	0.45	1.00		
Experience	0.22	0.43	-0.01	1.00	
Coordination	0.27	0.15	-0.12	0.28	1.00

A great variance is detected with regard to the coordination methods. Overall, each coordination procedure relies on 5 influencing factors which must be adapted according to the specific situation: milestones, department boundaries, project teams, trainings and expertise, and responsibilities. As pointed out in the first section, coordination methods between two functional units have been extensively researched in the past. It is important to notice that too much coordination can also result in an excess of bureaucracy.

Secondary factors. The technical complexity as well as the cost efficiency of the transition are rated as *secondary factors* (mean = 3.1 and mean = 2.8 respectively). Technical complexity links to the technological capabilities of the involved parties but most cases revealed that technical complexity does not significantly influence the likelihood of successful transitions as long as the aforesaid criteria are fulfilled.

”Higher technical complexity simply implies that one has to communicate more. The more complex the transition the more intensive you have to communicate.”

With cost efficiency we only refer to the transaction costs at the interfaces. It doesn’t incorporate overall development costs or general manufacturing costs. From this follows that most respondents reported that cost efficiency is not a decisive factor at the interfaces.

5. Conclusions

The interfaces of process development consist of heterogeneous relationships. Especially the varying objectives and the interdisciplinary requirements result in complex transitions. Against the background of these conditions our analysis contributes to a more complete understanding of the interfaces in process development. The aim of our explorative study is the disclosure of latent influencing factors and their interdependencies at the interfaces of process development. Therefore, we provide a conceptual model consisting of different dimensions of distance and inherent factors which are subsequently analyzed in greater detail. Thereby, we have shown which perspectives need to be incorporated in order to pursue a holistic optimization of transitions from and to process development.

Our analysis can only be regarded as a first step towards a more process oriented view of NPD. Many implications for the direction of future research result from the findings. For example, our examination of geographical distance in relation to other dimensions of distance has shown that in the future a more appropriate measurement of distance is needed if we want to empirically capture the notion of distance between two functional units.

The paper is limited to process development in biotechnology industry. However, we argue that the characteristics of biotechnology are also found in other high technology industries. Therefore, the analysis has general implications for practitioners forming interfaces in process development. Furthermore, we assume that findings about interfaces of process development can be transferred to interfaces of other functional units. Thus, the analysis is universally relevant to academics researching interfaces of functional units, in particular academics dealing with the concept of distance. Due to the rise of convoluted innovation economies, the management of interfaces will further gain in importance in the future.

The limited amount of quantitative data only allowed for a cross check of our qualitative results but a more reliable evaluation of the quantitative size of different effects is still needed. More quantitative studies will help to further curtail the drivers for success or failure at the interfaces of process development. The overall goal must be to enable a consistent management of NPD which eventually leads to more cost-efficient development of new products across various interfaces.

APPENDIX

Table A.1 | Overview of Respondents

Position	Duration	Field of Activity	Firm Size
Industrial biotechnology			
CEO	2 h, 25 min	Process; Supply/Services	Small
CEO	40 min	Supply/Services	Small
Project Leader	1 h, 39 min	Supply/Services	Small
CEO	55 min	Product; Process	Small
Group Leader	1 h, 14 min	Product; Process	Small
CSO/CTO	1 h,36 min	Product; Process	Medium
Project Leader	47 min	Process	Medium
Project Leader	1 h, 8 min	Product	Medium
Principle Scientist	50min	Process	Large
Project Leader	1 h, 32 min	Process	Large
Project Leader	1 h, 15 min	Process	Large
Group Leader	1 h, 23 min	Process	Large
Professor (with tenure)	1 h, 16 min	Supply/Services	Academia
Professor (with tenure)	58 min	Product	Academia
Medical biotechnology			
Project Leader	58 min	Product; Process	Medium
Group Leader	1 h, 58 min	Product; Process	Medium
CSO	47 min	Product	Medium
Project Leader	1 h, 54 min	Product; Process	Large
Group Leader	1 h,23 min	Process; Production	Large
Group Leader	1 h 39 min	Process; Production	Large
Project Leader	1 h, 4 min	Production	Large
Group Leader	1 h 59 min	Process; Supply/Services	Large
Project Leader	1 h, 48 min	Process	Large
Group Leader	1 h, 10 min	Process	Large
Professor (with tenure)	1 h, 4 min	Process	Academia
Professor (with tenure)	1 h, 7 min	Process	Academia
Industrial biotechnology & medical Biotechnology			
CEO	32 min	Supply/Services	Small
CTO	1 h 27 min	Process; Production	Small
CSO	1 h, 25 min	Product	Small
Principle Scientist	1 h, 18 min	Process; Supply/Services	Large
Professor (with tenure)	48 min	Product; Process	Academia

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