Pharmaceutical and Biotechnological Industry Case Studies

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Building on an exploratory study[1] of adult learning in five firms of the biopharmaceutical sector,[2] the aim of this study is to better understand the interrelation between formal and non formal learning practices in the new knowledge economy. We want to analyze the ways employees acquire and share new knowledge and skills in this high tech domain and to look more precisely at the different relations, either cumulative or contradictory, between formal and informal learning practices.

The methodology to observe and document organised learning is known and we have used it in the study quoted of bio-pharmaceutical organisations. However, documenting in context informal learning is more difficult. To that end we have made a specific review of the anthropological literature on contextual learning[3] where creative work has been done to develop new design for such study micro-level study. In complementarity to the survey approach inquiring directly on *declared* non formal practices, we were searching for a more ethnological way to observe *in situ,* that in the working process of teams of professional in the RnD sectors of the Biopharmaceutical industry.

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[1] Belanger,P. 2004, *L'organisation de la formation en entreprise,* Montreal, : CIRDEP/UQAM

[2] Comité sectoriel de main d'œuvre des industries des produits pharmaceutiques et biotechnologiques du Québec, 1999, *Portrait du secteur,* Québec : CSMOIPPBQ, 172p. - CONSEIL DE LA SCIENCE ET DE LA TECHNOLOGIE. *L'innovation, une exploration sectorielle : pour une politique québécoise de l'innovation (aérospatiale, pharmaceutique, produits forestiers)*, Québec, Gouvernement du Québec, 1998, p. 32, in Comité sectoriel de main-d'œuvre des industries des produits pharmaceutiques et biotechnologiques du Québec. *Industrie des produits pharmaceutiques et biotechnologiques*, sept. 1999..

[3] Lave, J., 1988, *Cognition in Practice, Mind, Mathematics and Culture in Everyday Life,* Cambridge: CUP; Lave, J. and Wenger, E., 1991, Situated learning: *Legitimate Peripheral Participation,* Cambridge: CUP; Wenger, E., 1998, *Communities of Practice: Learning, Meaning and Identity*, Cambridge: CUP)

Direct observation proved to be quasi impossible, because of time required and of resistance of the involved organisations to allow such an external presence inside. We then look for ways to reconstruct the individual and collective processes through which employees produce, acquire, transfer and use new knowledge and skills. To capture in action this reality, we borrowed the concept of Lave and Wenger (1991) of *legitimate peripheral participation.* However, instead of their approach consisting in <u>direct</u> <u>observation</u> of people at work (an approach developed also by the French school of "ergonomie du travail et de l'apprentissage"[4]), we are reconstructing, through interviews of members of working laboratory teams, the learning interrelations through the processes of gradual integration and mobility of newcomers and leavers in eight different working groups.

The Research and Development sections of the biopharmaceutical industry offer indeed a much heuristical context to look at this subtle reality, because of their peculiar organisation of work. Either for more upstream research where group of professional receive a, let say, 12 months mandate to search and create a new molecule in relation to a specific illness or medical needs, or, further down in the process of the creation of a new medicament, where a group of professional is formed with the specific task to validate the medicament through clinical research, each of these team is formed out of experienced and new professional who will have to work together during the prescribed period in order to achieve their mandate. They then offer to the researcher of informal learning a unique observatory.

<u>Research Design</u>

The research design, implemented in eight RnD working teams from four firms, has been created as a substitution for observation, by rebuilding the gradation of tasks in each of these eight teams and then reconstructing ways new comers proceed to master these and bring their

[4] Chatigny, C., 2001, *La construction de ressources opératoires. Contribution á la conception des conditions de formation en situation de travail.* Paris : Ministère de l'éducation nationale, de la recherche et de la technologie (Thèse de doctorat en ergonomie/CNAM). Teiger, C. et al., 1998, «Apports de l'ergonomie à la formation des opérateurs concernés par les transformations des activités de travail» in Dessaigne, M.F. & Gaillard, I. (ed.) *Des évolutions en ergonomie*, Toulouse :Octares 97-125

own input in the process. Only then, through this direct observation of informal learning in process and in context, will we be able to capture informal learning in action, and, then, look at ways people relate these to more formal learning events. Such a design will allow us, because of the eight different studied situation, to explore how the context and other factors facilitate or inhibit these learning processes, to look at the mediation processes between the economic driven learning demand and the individual needs and aspirations, to observe the impact of certain factors like aging and gender.

We will be, then in better research position to address the following critical questions:

- How the changing production context transforms the structured and informal learning dynamics and, reciprocally, how training and learning activities contribute to changes in production processes and in social relations within the organisation?
- How professional employees, in knowledge intensive industry, construct and upgrade their professional knowledge?
- How work environments induce and transform dynamics between informal and formal learning?
- How the social learning demand and its potentially contradictory components are being mediated and negotiated? What are the representations of the different actors on the various learning practices and approaches?

The field

It is extremely difficult to get the collaboration of the biopharmaceutical organisations because of the professional confidentiality of such productive processes of the work and of the time pressure. After months of dialogues, we got the consent of four firms that have agreed, in each case, for to give us access to two professional working groups, for a total of eight groups.

Firm A is part of a multinational corporation doing research, production and distribution of drugs. This corporation, with its headquarter in USA, has 49 plants operating in various parts of the world with more than 54 000 employees. The enterprise in Montreal has 1 200 employees involved in the three sectors of activity, including research.

Firm B is a small highly specialized enterprise doing only research, and, even more, only upstream research. The majority of its small staff of less than 60 persons has a post-graduate degree, if not a PH D in science. This small high tech enterprise is situated in the middle of the Montreal biopharmaceutical industrial park, hoping that its expected discovery will be bought by the large neighbour corporations for further development and production.

Firm C, like A, is active in all three field of work of the industry. They develop, test produce and distribute new drugs and medicine... Only in Montreal, this firm hires more than

2000 with 15% of them involved as scientific researchers. This multinational invest in research each year 30% of its profit, for an amount of 3.5 billions dollars.

Firm D, is a medium size enterprise with 300 employees involved also in the three areas. The researchers in D are doing more clinical research to test and validate drugs and medicine and applied research to find new ways to produce, on large scale. generic drugs.

In each of the four enterprises, we will produce a "portrait" of the firm and its context, as well as a picture of the various structured learning activities and the level as well as type of support given by these organizations to informal learning. In each of the eight working teams, we are make semi-structured interviews with four members (the leader, one "veteran" and two new comers) and administered a small questionnaire borrowing questions from the overall survey. Four months later, each of the interviewees will be contacted to complement the data-collecting.

The instrument for data collecting

The frame of reference for the interviews is illustrating well the original approach taken in this study to document and analyze informal learning. Based on the theory of peripheral legitimate participation, the analysis proceeds gradually at four levels, and each level dealing with the two essential dimension of work related learning: participation in the productive action and development of identity. This last dimension, based on Dubar's work (1991), is adding to the framework of Lave and Wenger, in order to take into account the relation between skill acquisition the changing socio-professional position of the subject, in order words, to use Lave borrowed to Marx concept, between the *use* and *exchange* value of learning and education. Finally at a fifth level, we attempt to depict the different relations between structured and informal learning in different contexts.

1. Level 1 Analysis of the organization of work in the working group,
2. Level 2 Tasks to be performed in chronological and in order of complexity,
3. Level 3 The gradual mastering of tasks : peripheral participation ,
4. Level 4 The dynamic of interrelation, information exchange and inter- learning
5. Level 5 The different relations between structured and informal learning in different contexts.

Operational Reference Framework

Level 1 Analysis of the organization of work in the working group		
Dimensions	*Sub-dimensions*	Indicators
Complexity	Description of the situation[5] and of the different tasks involved	• Description of the situation in terms of tasks (the most typical in order of progression and complexity, of roles, of areas of specific practices and of responsibility. • Indication of duration of tasks and of their visibility
Identity *(Profile of most competent team members)*	Status	• Indications on status attached to each or group of positions in the team, in particular of most recognized competent members (and when appropriate, professional title)
	Relations	• Hierarchical relations • Interrelation between colleagues (individual tasks and relation patterns in the team)
	Values	• Identification of legitimate authority (according to expertise, to recognized decision-making power, to speak on behalf of the team, rules keepers, group work coordination, informal leadership, …) • Identification of mandates and of prescribed tasks. • Identification of organisation's different goals.
Level 2 Tasks to be performed in chronological and in order of complexity		
Dimensions	*Sub-dimensions*	Indicators
Intensity	Types of activities	• Different implemented tasks and roles, their characteristics in chronological and

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[5] Team work and its overt interrelation pattern.

		"complexity" ranking order.
	Types of participation in the team	• The dynamics involved in the peripheral incrementing participation in relation to the complexity of the tasks and roles involved. • Indicators of progression through the tasks according to their complexity • Degree of peers' support (information, advice, observation, joint work, etc.)
	Degree of involvement	• Increasing degree of intensity in the implementation of the group's mandate. • Various level of involvement according to different tasks.
	Degree of approval and recognition	• Acknowledgement (positive or negative) by leaders and peers of task performed.
Identity *(manifestation of initial and progressive professional identity on the part of newcomers)*	Nominal categories	Mention of formal and professional accreditation and title
	Relation to hierarchy	• Reference to relations with superiors in term of recognition and non recognition. • Relation to an informal leader (professional and non professional)
	Access to power	• Indications on possibilities to gain influence and power position in the team (sharing decision-making, access to information, transmission of information, vertical mobility, etc.)
	Significant professional (model)	• Indications about (« significant others ») members who are source of admiration and professional referenced.
	Trajectory	• Identity in terms of professional project.

Level 3: The gradual mastering of tasks: peripheral participation

Dimensions	*Sub-dimensions*	Indicators

Intensity *(How tasks and roles are progressively mastered <u>peripheral participation</u>>)*	Ways of progressive acquisition of knowledge and skills, according to levels of complexity	• *General and technical knowledge and skills* • *Learning (self and otherwise) practices* • *team support to master complex tasks and roles* • *Contribution or non contribution of structured learning activities (see level 5)*
	Ways and means to acquire information and skills	• *Progressive mastering of tasks* • *Means of acquisition according to levels of complexity* • *Ways of getting access to information and learning and documentation*
Identity *(meaning given by new members to the progressive mastering of roles and acquisition of professional identity)*	Meaning given to being in control of new tasks and roles, to progression in expertise and recognized expertise.	• *Access* • *Legitimacy* • *Participation*
	Meaning given to acquisition of new identity in the team.	• *Development of identity* • *Contribution to and position in the team*

Level 4: The dynamic of interrelation, information exchange and inter-learning in the working group

Dimensions	*Sub-dimensions*	Indicators
Identity *(position, roles in the group hierarchy; interactions-relations; circulation of information; collaboration-conflicts; access-participation for each and all members)*	Access and participation; reproduction functions	• *Access to information et resources* • *Legitimacy of action* • *Participation* • *Types of functioning* • *Modes of cooperation / conflict*
	Patterns of interaction, types of exchanges, mapping of information and power (and leadership) interrelations (sociogram)	• *Relation of influence and power* • *Interactions* • *Types of exchanges,* • *Role and autonomy of action of different members* • *Hierarchy* • *Cooperation and conflicts*
	Climate, culture, team codes, legitimacy	• *Identity* • *Legitimacy* • *Team culture, codes*

Level 5		
Dimensions	*Sub-dimensions*	Indicators
Relation between structured and informal learning	Contribution of informal learning to the team and the fulfilment of its mandate	• *Retracing and going back to the various forms of informal learning of the above mentioned tasks*
	Contribution of structured learning to the team and the fulfilment its mandate	• *Contribution of structured learning activities to the mastering of tasks*
	Complementarity / substitution / inconsistency	• *Relations between informal learning and participation in structured learning activities*

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Project

The pharmaceutical and biotechnological industry, and more especially the biotechnology innovative, non-generic sub-sector, especially with regards both to its strong applied research component in a much specialized area and to the globalization of its market and the intense competition involved, constitutes a significant part of the New Economy. The rapid growth of the new knowledge intensive industry is observed as well in its Research and development section, as in its production units and its new pattern of relation to its market through clinical research and new "professional" distribution approach involving the mediation of health specialists and practitioners.

This sector in which "fast-paced radical innovations are crucial for success" (Lam 2002) is a heuristic one to study the relation between work organisation, intensive high-technology context and learning, and, more immediately, the changing learning practices and modes of knowledge transfer. This economic sector, already under pressure like many other industrial domains to develop "learning enterprises" (Senge 1990) because of the demand for "internal" flexibility coming from global competition. The growing integrated Research and Development component pushes also in this direction toward learning intensive organization. This economic sector is also operating under growing international and national health and drugs quality control as well as ethical norms that generates at all levels of its occupational hierarchy a demand for new approach for clinical research and testing as well as continuous review of techniques of production. Because of the contrasting qualification requirements observed between its R&D and line-production sub-sectors, this specific domain is furthermore of special research interest to study the relation between changing work organisation and various patterns of learning activities because of its diversified occupational population, of the coexistence of research and production activities, of the particular gender balance of its workforce (52% women), of the importance of its aged population (24.6% in the 45 to 54 year age bracket) and, finally, of the presence of immigrant employees. It will also analyze the way aged employees, at risk, cope in this learning intensive context (Bélanger, 1992) and will study a specific gender dimension looking at the critical biographical period (25-35) where reproductive momentum enters in conflict with the most intensive work-related adult learning phases. It will also observe the way immigrant specialists are integrated since it constitutes a critical economic and cultural dimension of this specific labour market, that is as an external source of innovation and high level competence (Cohen, S.S. and Field, G., 1999) and as members of a cultural minority both at the work-place and in the community. .

The two case-studies retained are two large-size bio-pharmaceutical non-generic firms, one unionized and the other none, both situated in Montreal (Quebec) where an innovative high-tech cluster of firms is emerging (Comité sectoriel, 1999). This economic sector is developing rapidly in Montreal not only because of the exceptional demographic context it offers for epidemiological research and clinical testing, but also because of its mobile and active labour occupational labour market, the possibility of inter-firms mobility and the growing landscape of large and medium-sized enterprises, as well as small high tech innovative firms. This typical context of the bio-tech sector (Hendersen et al., 1999) is of special interest because of the "occupational community

factor"(Lam, 2002), that is the inter-enterprise dimension of knowledge production and transfer and the tacit processes it facilitates.

More specifically, we will address four questions:

- What kind of and how learning formal and informal activities are organized and/or supported by enterprises ? What kind of formal and non formal activities are required by groups of employees to cope with the implementation of technical and organizational change? Who participates in what kind of learning activities?

- How the changing production context transforms these dynamics? How knowledge intensive activities and specific organizational/technical changes contribute to different type of training and learning activities? How different training and learning activities contribute to different changes in production processes and in social relations within the organisation? How the organisational process of increasing the qualification of jobs relates to the various ways taken by individuals to increase their qualification?

- How the different categories of workers construct their professional knowledge base learn? What is the relationship between the formal and informal as well as individual and collective knowledge construction and transfer processes? How different work environments induce specific dynamics between informal and formal learning, between tacit and explicit knowledge (Polanyi, 1966)? Under which contexts, organized learning tends to support or restrain the informal construction and transfer of operational knowledge ("par et dans l'action"), to mobilize tacit knowledge? How different training and education conditions tend to produce different learning dynamics?
- What role the different actors play in the enlarged decision processes from initial expression of learning demand to follow-up activities and assessment? What are the institutionalized and diffuse mediation processes taking place between the external production related learning demand and the subjective learning experience and aspirations of employees (Belanger, 2000, chap. 6)? What are the representations of the different actors about the learning strategy of the different actors and about the education and training policies of the firm and its approach toward informal learning?

The difficulty in such case-studies is to document the different relation patterns between organized and non formal learning in the different work contexts and to study the supply-demand interactive theories within enterprises at local level. The challenge is to research the learning strategy of the organisation and of its different departments as well as to capture, at the micro level, the tension between the prescribed and the real tasks (Teiger, 1998) and the implicit learning and inter learning processes that tends to take place. Only then, will we be in position to relate organized participation to training to these various possible "communities of practice".

To that end, the research design will combine, through a specific sequence, observation, semi-structured interviews, micro-observation and small focus groups and will be implemented in each of the two firms.

First year

- Production, with the "education and training contact person," a differentiated picture of the organized education and training activities, that have taken place during the last two years, and of the explicit support and recognition given to informal learning,
- Observation phase with unstructured interviews in both the research and the production units allowing us to grasp the different internal contexts and learn the "codes" used to speak about knowledge and skill transfer in order to finalize the questionnaire for the next phase,
- Administration of semi-structures interviews that will be administered with representatives of general management, of the human resource and personnel department, of the education service, of directions of operation, representative of employees, groups of employees, and representatives of involved external education and training agencies.

Second year
- Direct observations (*open* observation leading to *systematic* observation using defined indicators) completed all along with a series of short work-task related interviews, using the methodology developed in work ergonomic research (Guérin et al.,1997), since implicit individual and collective learning and learning transfer processes can be best observed and understood at the work place (Teiger 1993, 1998; Chatigny, 2002). Such approach allows "la mise en mots de ce qu'on ne sait pas qu'on sait, ou qu'on sait sans avoir jamais pu le parler" (quoted by Chatigny). This will be done with small group employees (some being current participants in organized learning) in one research and in one production section selected in each of the two firms.
- Follow-up short interviews with individual and groups met in the first round for a phase of co-analysis with the different actors.

Paul Bélanger is already conducting a study on the institutionalization of formal learning and of support to informal learning in this specific sector, a project undertaken in partnership with the "Commission des partenaires du marché du travail du Québec" and the "Comité sectoriel de main d'œuvre des industries des produits pharmaceutiques et biotechnologiques du Québec".

Building on a current exploratory study of adult learning in three firms of this sector, a case-study will be made in two large pharmaceutical and biotech enterprise in Montreal area. The aim is to analyze the ways employees produce, acquire, transfer and use new knowledge and skills in this high tech domain characterized by continuing innovation and recurrent adjustment of techniques of production, as well as the factors supporting or inhibiting organized and informal learning, to the impact of the different work contexts between the R&D and the line-production sub-sectors, to the different cumulative, conflict or weak relation patterns between formal and informal learning practices, to the formal and informal negotiation process between the economic demand and the individual needs an aspirations (i.e. the supply-demand

interactive theories). Special attention will be given to the aging and immigrants workers, as well as to the gender factor especially at critical moment of the occupational biography.

The research design, to be implemented in each of the two firms during a two years period, combines, through a specific sequence, observation, semi-structured interviews, special micro-observation completed by small focus groups and follow-up co-analysis interviews.

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