1
Principles of Industry Immersion Learning

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Industry Immersion Learning. Real-Life Industry Case-Studies in Biotechnology and Business
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Abbreviations

GMP = Good Manufacturing Practice
cGMP = current Good Manufacturing Practice
GLP = Good Laboratory Practice
CEO = Chief Executive Officer
FDA = Food and Drug Administration
SWOT = Strengths, Weaknesses, Opportunities, Threats

1.1 Introduction

Traditionally, universities have produced the same kind of employees for both academic and industry work environments. The industry work environment has changed dramatically during the last two decades and the skill set needed in industry today is very different from the one needed in academia. It includes a high level of technical aptitude, multiple professional competencies, an interdisciplinary, highly flexible, and collaborative attitude, and a globally oriented perspective.

Coming from a traditional university training, graduating students face a highly challenging work environment when they enter industry careers. The university education is typically acquired through content-oriented classroom lectures and hands-on laboratory work. It promotes the students' analytical and individual skill sets and their ability to compete. Students gain a sharply defined amount of understanding in discrete topics, often in a nonintegrative manner. Industry needs a workforce with skills that both include the academic background and extend it. Prospective employees need to learn about industry-relevant topics, to understand and be able to operate in a context-oriented manner, to think innovatively, and to develop and utilize good communication and interpersonal skills through teamwork and networking.

As a response to this need, universities in the United States and elsewhere are showing interest in need-based curricula and a concept called "professional Master's education". The goal is to tailor professional graduate education to meet employers' needs. These degree programs focus on developing employer-relevant education, primarily by including new topics and often multi- and/or interdisciplinary training in their curricula. The programs vary in their levels of interaction with industry. An example of this type of program which employs multifaceted interaction with many industry professionals in the Research Triangle Park, North Carolina, is the professional Master's program in Microbial Biotechnology at North Carolina State University. This program integrates academic and professional training in both business and science. Students learn work-force-related skills through industry internships, via industry mentors, and in a new course entitled "Industry Case Studies". This course is interdisciplinary and encompasses a variety of business and science initiatives. The Industry Case Studies course serendipitously utilizes components of action-based learning and context- and problem-based learning that involves cutting-edge unresolved projects and teamwork. The case studies are often "open-ended" which means there is a certain amount of flexibility concerning the topic and the outcome. This course is currently the only one of its kind; it employs so-called "industry immersion learning" and is tailored specifically to the biotechnology and pharmaceutical work environments in the Research Triangle Park. The following sections describe how this course was developed. Sections 1.2 and 1.3 have been reprinted with permission from *Journal of the Academy of Business education*.

1.2 Building a University – Industry Alliance

1.2.1 Educational Needs Assessment

In order to create employer-relevant education it is essential to become knowledgeable about the employers' needs. An effective way to identify immediate training needs is to survey professional employers regarding which skills graduates should have in order to obtain employment. Another method is the creation of an inventory map of employers, their fields of expertise, technology, market, size, and predicted growth in a particular area. Using a compilation of these methods, a list of highly desirable skills for graduate-level employees has been assembled (Table 1.1). Many of these represent a large challenge for universities, and effective training in these areas often requires a high level of interaction with professionals. This interaction can take many forms including internships, guest instruction on projects/case studies, guest lectures, and mentoring.

1.2.2 Establishing Contact

After the determination of educational needs and resources, key contributors from industry must be identified. This process involves research of individual industry professionals, their positions and responsibilities, fields of expertise, and level of interest and skills in curriculum design and teaching. Phone calls and visits must be made and often followed up with numerous meetings to discuss the scope and length of the interaction, necessary resources, and format. The interaction must be initiated at the correct level. The industry professional should have the flexibility to make the decision to interact with academia without jeopardizing company interests. As an example, a request for interaction is more likely to receive a response from the chief executive officer (CEO) of a small (less than 50 employees) or medium-sized company (50–500 employees) than from the CEO of a large company (more than 500 employees). This is a reflection of responsibilities and resource constraints. Table 1.2 lists examples of key contributing industry professionals according to their position and the size of the company in which they are employed.

Table 1.1 Skills in high demand in the biotechnology and pharmaceutical industries.

Competency category	Discipline
1. Academic	Science
	Business
	Integration of science and business
	Analytical thinking
2. Practical experience	Internship
	Bench and office work
3. Technological	Research and development process
	Manufacturing process
	Clinical trials process
4. Specialty	Intellectual property
	Regulatory knowledge
	GMP/GLP exposure
	Project management
	Accounting and introductory
	Finance
5. Soft skills	Leadership
	Mentorship
	Teambuilding
	Conflict management
	Expectation management
	Change management
	Ambiguity management
	Communication skills
6. Mindset	Context-oriented thinking
	Out-of-the-box focus
	Entrepreneurship
	Global orientation

GMP, good manufacturing practice; GLP, good laboratory practice

Table 1.2 Industry professionals: rank of contact person and company size.

Contact person	Company size
Team leader	Large
Manager	Large
Director	Large
Vice president	Large
Director	Medium
Vice president	Medium
Vice president	Small
CEO	Small

1.2.3 Marketing Incentives

Clearly describing the advantages of collaborative teaching is essential for alliance building. As examples, industry professionals have an opportunity to:

- obtain resources through student work and new ideas;
- train students in skills of importance for industry;
- evaluate students for future employment;
- gain access to potential employees.

Academics, in return, have the potential to access new technology, interdisciplinary thinking, and know-how, as well as to gain a professional network by interacting with industry professionals.

1.2.4 Obtaining Commitment

After initial interest has been spurred, reciprocal goals must be set. Flexibility should be displayed in any or all of the following areas: timing, length of project, participating instructors, specific deliverables (such as reports and presentations), intellectual property matters, and geographical logistics. Intellectual property is often a matter of great concern for both parties. Universities typically want to protect students and faculty from signing unnecessary contracts of restraint and desire to limit the length of the contract. Industry professionals, on the contrary, have a duty to protect the intellectual property and trade secrets owned by the company of employment. Agreements that provide for nonconfidential interaction are easier to manage, but the outcomes are limited by disclosure restrictions (see also 1.8.7 Legal Requirements).

1.2.5 Alliance Dynamics

Many factors influence the dynamics of the academia–industry interaction. If the interaction is deemed positive, it is likely to continue and become an asset for both parties and an opportunity for further development. External factors play an important role and can cause unexpected change with demands on flexibility. Examples might include sudden travel arrangements, unforeseen audits, termination of employment, relocation, company reorganization, altered priorities caused by market forces, lack of resources, promotions, mergers and acquisitions, and personal reasons. Success and maintenance of an interaction between industry professionals and academics are subject to such changes, and the ability to quickly adjust to alternative strategies when change happens is essential.

1.3 Design, Format, and Model Examples of Case Studies

The broad scope of intellectual exchange defined by alliances becomes a useful platform for innovation. Due to the synergistic nature of the interaction, new education not normally employed at universities is being created; an example is the Industry Case Studies course. Industry professionals and faculty discuss matters concomitantly from both an industry and a university perspective. They decide topics, process and teaching methods, duration, geographical location, resource allocation, deliverables, and target audience for final presentations. They discuss and resolve legal matters and may agree to publicize the interaction with academia and with the students through press releases or other media. Table 1.3 displays a summary of case studies as they were created and performed in the period from August 2003 (program launch) to May 2008. All case studies target the core competencies listed in Table 1.1 and involve the study of a specific forefront issue in science and/or business.

1.3.1 Example 1: Technology Development

Case study #5 focused on the manufacture of enzymes and was performed at a large biotechnology company. Students learned about the process of enzyme

Table 1.3 Examples of case studies and timelines.

Case study	Topic	Duration
1	Gene expression	3 weeks
2	High throughput diagnostics	4 weeks
3	Modified crops	4 weeks
4	Bioremediation	4 weeks
5	Technology development	4 weeks
6	Quality assurance, cGMP training	7 weeks
7	Biomarkers *(Chapter 2)*	6 weeks
8	Communication skills, conflict management	2 weeks
9	Patent law *(Chapter 5)*	8 weeks
10	Product assessment	4 weeks
11	FDA audit	2 weeks
12	Business development	11 weeks
13	Project management *(Chapter 3)*	8 weeks
14	Human error prevention *(Chapter 8)*	8 weeks
15	Intellectual property management *(Chapter 6)*	8 weeks
16	Outsourcing vs. in-house technology	6 weeks
17	Entrepreneurship *(Chapter 4)*	8 weeks
18	Operational excellence in manufacturing *(Chapter 7)*	8 weeks
19	Real-time monitoring of contamination and resources	12 weeks
20	Minimizing company environmental footprint	12 weeks

cGMP, current good manufacturing practice; FDA, Food and Drug Administration.

production and were tasked to create methods to minimize fouling on filtration membranes by microorganisms (the occurrence of so-called "biofilm"). Students worked to comprehend a variety of issues in the areas of microbiology, biochemistry, molecular biology, and engineering. They suggested a mix of physical, chemical, and biological barriers as a means to reduce biofilms. The students finalized the project with a report and a presentation for the employees at the plant. The case study gave the students an opportunity to work as entrepreneurs on an important problem in industry, work interdisciplinarily, practice teamwork, improve their oral and written communication skills, and present their ideas to a large heterogeneous group of industry professionals including laboratory staff members and executive officers.

1.3.2 Example 2: Product Assessment

Case study #10 took place in a medium-sized biotechnology company. The project involved analysis of a confidential new product. Students were divided into two teams, a business team and a science team. The business team was tasked to perform a market analysis, investigate the intellectual property status, develop a budget, and predict the profit margin. The science team developed protocols, proposed a timeline for production, assessed the development costs, and considered compliance issues. Together the teams developed a business plan and gave their recommendations. Students developed an understanding of the challenges of science and business teams working together, components of a business plan, assessing the viability of a product, justifying the assessment to an executive management team, and maintaining professional conduct while working on a confidential project.

1.3.3 Example 3: Business Development

The goal of case study #12 was innovation and marketing of new products containing antioxidants. This study was carried out in a large pharmaceutical company. The students performed a cost–benefit analysis and a market analysis that included identifying the current competition. They studied a variety of antioxidants and compiled and summarized large amounts of data on the biochemical pathways involved including toxicological and pharmacokinetic aspects. The students decided to present to the management team product ideas useful for both prophylaxis and treatment of selected conditions. During the process many product ideas were deemed not profitable and subsequently rejected. This study gave the students an opportunity to comprehend the amount of business and science information that is necessary to analyze a new product idea, learn that projects are often terminated and that flexibility is a necessary skill, design a new product, market their product idea in a corporate forum, and discuss their product idea with a professional management team.

1.4 Basics of Industry Immersion Learning

1.4.1 Definition and Characterization

Immersion learning is defined here as the learning that occurs as a result of immersion in a particular environment. Therefore, it is characterized as an environment-related and environment-preparative method that employs aspects of multiple learning methods in addition to its unique environmentally dependent features.

1.4.2 The Immersion Environment

Before immersion learning can be initiated, industry professionals and academics must have agreed to and prepared projects within the relevant frameworks for the students. Because the projects typically are open-ended, there is no result indication beforehand, and often projects address high-risk areas in need of investigation and resources. Consequently, students are placed directly in the relevant environment, which may be unfamiliar, or slightly familiar, or even familiar to them. Because work environments and companies vary, no learning obtained in one environment will be absolutely replicable in another. This adds to the potential for understanding context.

1.4.3 Sample Work Flow of an Immersion Case Study

Teams of students are given rudimentary but necessary precursory information and training to present goals for the project, a plan for their activities, and a list of the deliverables (e.g., reports and presentations) they will provide. This plan must be accepted by the industry professionals, after which the students will be left to pursue their plan. This often requires extensive information exchange and building and creating of discussion networks on- and off-site as well as adjusting project goals and terms. The students finish the project by presenting their recommendations to the upper management in charge of the project and accepting feedback, questions, and suggestions for new deliverables.

1.4.4 Interactive Agents

One of the advantages of the immersion learning method is the need to find information that is not readily available in traditional formats (databases, textbooks, libraries, etc.). Students must seek advice and information from many sources, such as industry professionals, academics, vendors, catalogues, patent databases, to mention a few examples. They learn to identify and create alliances with these parties in order to achieve their goals, deadlines, and deliverables. In addition, students are coached by managers of the projects as well as the academics overseeing the immersion education, which create opportunities for understanding aspects from the viewpoint of both environments.

1.5 Predicted Learning Outcomes

There are four primary categories of immersion learning. These are: (1) specialty knowledge related to the environment, (2) professional, compliant conduct related to the environment, (3) interpersonal, communication, and networking skills, and (4) entrepreneurial mindset. The extent and type of learning can vary depending on how familiar the students are with the topic and the environment before immersion.

It is expected that students will adjust to the immersion environment and adapt attitudes and behaviors compliant with the particular environment's guidelines. Students are expected to learn by "living" in the environment and by permitting "knowledge diffusion" from the environment. The learning is expected to be context-oriented and related to topics and conduct relevant for the environment.

Because industry immersion fosters extraversion, interaction, teamwork, and networking, students are expected to develop their communication, and interpersonal skills as well as to become comfortable working in teams. It is expected that students learn to interact well with others, to share their ideas, and to contribute in a consistent manner to group goals while maintaining personal integrity, responsibility, and a professional identity. In addition, students are learning to manage unforeseen challenges relating to the specific environment. These can take the form of changes in a variety of parameters such as group composition, topic matter, deadlines, and instructor availability.

Innovative thinking constitutes another expectation. Students are stimulated to solve as yet unsolved problems with real-life implications. Most students find this very intriguing. They must decide how to proceed and how and where to retrieve information to make valuable recommendations. Because both team and personal reputations (including academic grades and later job opportunities) will be influenced by the quality of the work the students produce, they have strong incentives to excel.

1.6 Assessment of Actual Learning Outcomes

Due to the very complex nature of industry immersion learning, it can be an elaborate task to measure its outcome. Understanding additional learning parameters can be achieved by observing the actual challenges the immersion teaching method causes during the teaching period. In addition, students may reflect on their learning in a long range of areas such as the level of acquisition of science and business knowledge, presentation skills, interpersonal skills, flexibility, discipline, ambiguity management, cross-cultural understanding, and entrepreneurship.

1.7 Overview of Selected Case Studies

This book contains seven examples of educational industry case studies contributed by experts in various areas of biotechnology. These are by no means exhaustive of the field or an attempt to mimic a textbook; rather, these industry case studies represent highly selective subject matter for advanced students. The case studies include important topics such as:

- An overview of diagnostics technology and the challenges in drug discovery linking the identification and treatment of certain conditions
- Important considerations that arise when companies decide how to prioritize certain conditions and treatments
- Analysis of new business ideas and how to start new companies based on these ideas
- How to become knowledgeable about intellectual property and how to protect it
- How to organize and manage intellectual property and obtain an overview of the intellectual property landscape
- Introduction to the concept of operational excellence through systematic improvement of technology and processes
- Understanding how humans cause errors and how companies can attempt to remove the root causes of such errors

The first case study describes *personalized medicine* and is contributed by Michael Stocum. This chapter provides learning about the development of personalized medicines, drug discovery, biomarkers, breast cancer, and a breast cancer drug tailored to a specific segment of the population. This case study was taught during spring 2004.

Alan Woodall is the contributor of the second case study, a study of *drug portfolio management* with a focus on drug development choice and prioritization from the company perspective. This case study was taught during spring 2005 and 2007.

The third case study, in *entrepreneurship*, provides an outline of what is necessary to start a company. Cedric Pearce contributes this case study, which involves many important phases of entrepreneurship, such as conceiving and analyzing a business idea and writing a business plan. This case study was taught during spring 2006 and 2007.

Understanding of patent law is essential for all companies. Elaine Sale contributes the fourth case study, which provides basic knowledge about this topic. This case study was taught during fall 2004.

The *management of intellectual property* and how to develop a strategic and well-balanced overview of the competition and prospects are the subjects of the fifth case study, provided by Bill Barrett. This case study was taught during spring 2006.

Lucia Clontz contributes the sixth case study, which consists of two sub case studies in the area of *operational excellence*. She addresses both process optimization and technology improvement. This case study was taught during fall 2006.

Finally, the seventh case study addresses how humans can be taught to make fewer mistakes. Amy Peterson and John Shaeffer both work in the area of *job observation*, a discipline that focuses on preventing errors rather than reacting to them after they have occurred. This case study was taught during fall 2005.

1.8 Logistics of Industry Immersion Teaching

1.8.1 Topic Selection

When choosing a subject of study, it is essential that the topic is timely and of high priority in industry. Most often, a topic lends itself to additional and related topics because immersion learning is context-based. An instructor in industry immersion education will quickly realize that there are many opportunities for teaching and learning beyond the subject matter. I will illustrate this fact by using the industry case studies in this book as examples; Table 1.4 lists the subjects of study and the anticipated areas of learning together with some of the extended teaching opportunities.

1.8.2 Instructor and Instructor Affiliation

Industry topics are best taught by experts in the particular field. A willing expert is an individual who is knowledgeable about the field and abreast of issues relating to the topic, who has extensive experience, and who is available to perform or assist with teaching. It is wise to select instructors affiliated with companies that display sincere interest in the topic through relevant research and development efforts.

Table 1.4 Case study topics, anticipated learning and additional teaching opportunities.

Case study topic	Anticipated learning	Examples of extended teaching opportunities
Biomarkers	Diagnostics Drug discovery Co-development of drugs and diagnostics Translational research Breast cancer Personalized medicine Generic product profile	Genomics Molecular biology Cancer SWOT analysis
Drug portfolio management	Financial assessment concepts Financial assessment methods Target product profile Drug discovery Alzheimer's disease Anxiety Analgesia Cognitive enhancement Nicotine addiction	FDA regulations Marketing Communication Elevator speech Market analysis
Entrepreneurship	Entrepreneur characteristics Business plan Company organization Analysis of new business idea Ways to finance a business venture Innovation	Market analysis Grant writing Elevator speech Public presentations Marketing
Patent law	United States patent law Claims language Understanding inventions Protection of intellectual property Basic intellectual property transactions	Genomics Molecular biology Drug discovery FDA regulations Intellectual property and globalization Erythropoietin Biotechnology
Intellectual property management	Patent searching Patent mapping Patent claiming strategy	Genomics Drug discovery FDA regulations Biotechnology Presentation of large data sets
Operational excellence	Drug manufacturing Operational excellence Standards in manufacturing FDA regulations Six Sigma Lean manufacturing Biofilms	Drug manufacturing (detailed) Technology in the pharmaceutical industry Microbiology Engineering

Table 1.4 (continued)

Case study topic	Anticipated learning	Examples of extended teaching opportunities
Job observation	Operation modes Human error prevention Drug manufacturing FDA regulations Job observation Positive reinforcement planning	Job modification Marketing Drug discovery Compliance Communication

SWOT, strengths, weaknesses, opportunities, threats; FDA, Food and Drug Administration.

1.8.3
Timeline

The timeline for a case study can vary and depends on instructor availability, company needs, instructor goals, and student deliverables. For example, a particular instructor may be available only two weeks in a semester, whereas another instructor may be present the entire semester. If the company is using a case study to “get a job done”, for which otherwise the company would have limited or no resources, this is an incentive to tailor the timeline for the case study according to goals and student deliverables rather than to a specific amount of time. The case studies in this book have a length of six to eight weeks, with students meeting for sessions once per week. This study period can be decreased by increasing the number of sessions per week or by altering the assignments. Likewise, the study period can be extended by adding assignments or allowing more time for the execution of the proposed assignments.

1.8.4
Location

Industry immersion learning is optimal when it takes place in industry settings. However, sometimes it is necessary to use less ideal settings, for example, classrooms at universities. The circumstances that will determine the location can be addressed by asking the following questions:

1. Availability:
   (a) Are there a company and an instructor affiliated with the company in the vicinity?
   (b) Is there a conference room or laboratory available at the company site?
   (c) Are there computers or other important technical support for the students?

2. Attainability:
   (a) Is it possible to secure the resources necessary within the defined timeframe?
   (b) Are all legal requirements being met?
3. Practicality:
   (a) Is it possible for the students to arrive at the location in time for class and also to depart from the location in time for other classes?
   (b) Is it possible for students to arrange transportation to the location?
   (c) Is parking available?
4. Optimal environment:
   (a) Is the location conducive to industry learning?
   (b) Is learning dependent on a certain location, i.e., does the learning require a company setting or can it be performed in a university classroom setting?

1.8.5 Teaching Format

Learning about industry includes learning to function in a typical industry atmosphere. Therefore, it is essential that students learn to function well in teams, to listen well, to adopt the necessary flexibility and discipline, as well as to absorb the required technical skills. A variety of teaching formats creates the optimal learning experience. As an example, students need a certain amount of base knowledge before they can perform specific tasks in industry. Such knowledge can be provided in the form of lectures, homework, and team training, or by simple research assignments. More creative assignments often demand a higher level of interaction between industry instructors and team members. This phase is characterized by interactive learning through discussions and participatory problem solving as well as out-of-the-box thinking.

1.8.6 Student Deliverables

When possible, the industry environment should be mimicked as much as possible both in terms of the deliverable and the delivery. Student deliverables such as reports and presentations should resemble those assembled by employees in a company. These can vary widely, and examples include, board presentations, business recommendations, market analyses, business plans, technical documents, management documents, and intellectual property documents. Delivery may be practiced in a formal setting and while wearing business attire to pursue the maximum “learning-by-doing” effect.

1.8.7 Legal Requirements

Industry instructors and their affiliated companies are most often required to protect their intellectual property. This means that students and academic advisors often must sign certain legal documents, for example, confidentiality agreements and agreements relating to transfer of information. Such documents are commonly exchanged between companies. They relate to the information that will be shared, the location and people covered by the agreement, innovation that may take place, and presentation of confidential information. It is important for the establishment of industry immersion education that universities are willing to sign and honor such agreements.

1.9 Publishing of Industry Immersion Case Studies

Industry immersion teaching can initially be a rather resource-consuming endeavor. Being able to re-use teaching materials means conserving resources and thereby potentially increasing the audience. This can be achieved by publishing and disseminating the individual industry immersion case studies. However, industry instructors must ensure that publishing is in compliance with their company's legal regulations and policies.

This book is an example of the willingness and ability of many industry instructors in the Research Triangle Park, North Carolina, to give their time and expertise to students and to find the flexibility and support in their companies to provide such services. Each chapter contains an introduction to a "real-life" topic, the actual case study, followed by an overview of the timeline, teaching plan, and assignments. For most chapters web presentations introducing each topic can be found at www.wiley-vch.de/supplements/. It is my hope that both students and instructors will continue to find this material invaluable for understanding industry topics as well as a constant inspiration to personalizing new educational case studies in their own environments.