L. Borbye, M. Stocum, A. Woodall, C. Pearce, E. Sale,
W. Barrett, L. Clontz, A. Peterson, and J. Shaeffer

WILEY-BLACKWELL

Industry Immersion Learning

Real-Life Industry Case-Studies in Biotechnology and Business

Lisbeth Borbye, Michael Stocum, Alan Woodall,
Cedric Pearce, Elaine Sale, William Barrett, Lucia Clontz,
Amy Peterson, and John Shaeffer

Industry Immersion Learning

Real-Life Industry Case-Studies
in Biotechnology and Business

江苏工业学院图书馆
藏书章

WILEY-
BLACKWELL

WILEY-VCH Verlag GmbH & Co. KGaA

The Authors

Dr. Lisbeth Borbye

Michael Stocum

Alan Woodall

Cedric Pearce

Elaine Sale

William Barrett

Lucia Clontz

Amy Peterson

John Shaeffer

All books published by Wiley-VCH are carefully produced. Nevertheless, authors, editors, and publisher do not warrant the information contained in these books, including this book, to be free of errors. Readers are advised to keep in mind that statements, data, illustrations, procedural details or other items may inadvertently be inaccurate.

Library of Congress Card No.: applied for

British Library Cataloguing-in-Publication Data
A catalogue record for this book is available from the British Library

Bibliographic information published by the Deutsche Nationalbibliothek
The Deutsche Nationalbibliothek lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data are available on the Internet at http://dnb.d-nb.de

© 2009 WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim, Germany

All rights reserved (including those of translation into other languages). No part of this book may be reproduced in any form – by photoprinting, microfilm, or any other means – nor transmitted or translated into a machine language without written permission from the publishers. Registered names, trademarks, etc. used in this book, even when not specifically marked as such, are not to be considered unprotected by law.

Composition K+V Fotosatz GmbH, Beerfelden
Printing betz-druck GmbH, Darmstadt
Bookbinding Litges & Dopf GmbH, Heppenheim

Printed in the Federal Republic of Germany
Printed on acid-free paper

ISBN 978-3-527-32408-8

Lisbeth Borbye, Michael Stocum,
Alan Woodall, Cedric Pearce,
Elaine Sale, William Barrett,
Lucia Clontz, Amy Peterson,
and John Shaeffer

Industry Immersion Learning

Related Titles

Behme, S.

Manufacturing of Pharmaceutical Proteins

2009
ISBN: 978-3-527-32444-6

Gruber, A.C.

Biotech Funding Trends
Insights from Entrepreneurs and Investors

2009
ISBN: 978-3-527-32435-4

Meibohm, B. (ed.)

Pharmacokinetics and Pharmacodynamics of Biotech Drugs
Principles and Case Studies in Drug Development

2006
ISBN: 978-3-527-31408-9

Kerzner, H.

Project Management Case Studies

2005
ISBN: 978-0-471-75167-0

此为试读,需要完整PDF请访问: www.ertongbook.com

Preface

Graduates who secure their first jobs in industry typically spend a significant amount of time adjusting to the new environment because it is so different from the traditional university setting. Together with multiple industry professionals in the Research Triangle Park, North Carolina, I have introduced a learning method called "industry immersion learning" with the goal of easing the transition from the university to the workplace (here, the biotechnology industry).

The industry immersion method is characterized by need-based, innovation-oriented, and proactive acquisition of knowledge. The education is coordinated and supervised by academic and industry professionals in concert and promotes a high level of interaction between students and industry professionals. As the name of the method implies, students are immersed in the industry environment and tasked to excel in matters of high relevance to the company in which the training takes place. Students must adapt quickly to the new environment, create a professional network on site, become knowledgeable about the topic of study, employ innovative thinking, and meet or exceed expectations in their deliverables in a timely manner in order to succeed.

The industry immersion method has been received with enthusiasm among students and both university and industry leaders. It provides a means for the students to graduate with an industry-relevant education, and the university to provide industry with a better prepared, industry-ready workforce while simultaneously creating important university–industry networks and empowering employers to participate in curriculum design.

In an attempt to disseminate the method to a larger audience, employer alliance building and the industry immersion method are described in detail in this book, and seven industry projects, the so-called "case studies", have been compiled and transposed to a format useful in both industry and classroom settings. Each of these sample industry case studies focuses on a particular trend and together they provide a nonexhaustive view into selected, timely topics. The logistics of teaching by immersion are outlined and a variety of parameters can be customized to match the environment in which they are taught. By consolidating these examples of industry case studies in this book, I encourage their "re-use" while simultaneously hoping to inspire the creation of many new case studies and much new collaboration between universities and industry.

Industry Immersion Learning. Real-Life Industry Case-Studies in Biotechnology and Business
L. Borbye, M. Stocum, A. Woodall, C. Pearce, E. Sale, W. Barrett, L. Clontz, A. Peterson, J. Shaeffer
Copyright © 2009 WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim
ISBN: 978-3-527-32408-8

I am greatly indebted to the many industry professionals who have volunteered their time, expertise, effort, and enthusiasm to help me establish industry immersion learning at North Carolina State University. I am also grateful to the many students who bravely embraced the industry case studies and industry immersion education, displayed immense personal and professional growth, and commenced exciting careers with a skills set aligned with employers' needs.

The generosity of the North Carolina Biotechnology Center made this publication possible.

Raleigh, December 2008 *L. Borbye*

Disclaimer

The content of this book is based on the individual authors' personal knowledge and experiences. This book presents selected topics in the biotechnology and pharmaceutical industries. Mentioned laws, regulations, and guidelines are based on current status at the time of the authors' experience or writing. Each author is solely responsible for the content of his or her own chapter. The authors and editor disclaim any liability or loss in connection with use of the information herein. Use of the information is at own risk.

The contents of this publication and related links do not constitute legal or professional advice. Readers should not act or rely on any information in this book without first seeking the advice of an attorney or other relevant expert.

No part of this publication and the web presentations may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of the publisher and relevant author(s).

Industry Immersion Learning. Real-Life Industry Case-Studies in Biotechnology and Business
L. Borbye, M. Stocum, A. Woodall, C. Pearce, E. Sale, W. Barrett, L. Clontz, A. Peterson, J. Shaeffer
Copyright © 2009 WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim
ISBN: 978-3-527-32408-8

Contents

Preface *XV*

Disclaimer *XVII*

1 **Principles of Industry Immersion Learning** *1*
Lisbeth Borbye

1.1 Introduction *2*
1.2 Building a University – Industry Alliance *3*
1.2.1 Educational Needs Assessment *3*
1.2.2 Establishing Contact *3*
1.2.3 Marketing Incentives *5*
1.2.4 Obtaining Commitment *5*
1.2.5 Alliance Dynamics *5*
1.3 Design, Format, and Model Examples of Case Studies *6*
1.3.1 Example 1: Technology Development *6*
1.3.2 Example 2: Product Assessment *7*
1.3.3 Example 3: Business Development *7*
1.4 Basics of Industry Immersion Learning *8*
1.4.1 Definition and Characterization *8*
1.4.2 The Immersion Environment *8*
1.4.3 Sample Work Flow of an Immersion Case Study *8*
1.4.4 Interactive Agents *8*
1.5 Predicted Learning Outcomes *9*
1.6 Assessment of Actual Learning Outcomes *10*
1.7 Overview of Selected Case Studies *10*
1.8 Logistics of Industry Immersion Teaching *11*
1.8.1 Topic Selection *11*
1.8.2 Instructor and Instructor Affiliation *11*
1.8.3 Timeline *13*
1.8.4 Location *13*
1.8.5 Teaching Format *14*
1.8.6 Student Deliverables *14*

Industry Immersion Learning. Real-Life Industry Case-Studies in Biotechnology and Business
L. Borbye, M. Stocum, A. Woodall, C. Pearce, E. Sale, W. Barrett, L. Clontz, A. Peterson, J. Shaeffer
Copyright © 2009 WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim
ISBN: 978-3-527-32408-8

1.8.7 Legal Requirements *15*
1.9 Publishing of Industry Immersion Case Studies *15*

2 Integration of Pharmaceutical and Diagnostic Co-Development and Commercialization: Adding Value to Therapeutics by Applying Biomarkers *17*
Michael Stocum

2.1 Mission *18*
2.2 Goals *18*
2.3 Predicted Learning Outcomes *19*
2.4 Introduction *19*
2.4.1 Current Environment for Pharmaceutical and Diagnostic Product Development *21*
2.4.2 Potential Solutions to the Challenges Confronting Pharma *25*
2.4.2.1 Genomics and Proteomics, Metabolomics, and "Other -omics" *25*
2.4.2.2 Translational Research *26*
2.4.2.3 Biomarkers *26*
2.4.3 Drug Development for Targeted Cancer Therapies *27*
2.4.3.1 Tamoxifen in Estrogen-Receptor-Positive Breast Cancer *27*
2.4.3.2 Trastuzumab (Herceptin) in Breast Cancers Overexpressing Her2 *28*
2.4.3.3 Imatinib (Gleevec) in Chronic Myelogenous Leukemia and Gastrointestinal Stromal Tumors *29*
2.4.3.4 Other Targeted Therapies *30*
2.4.4 Specific Example of Lapatinib (Tykerb) *30*
2.4.4.1 Leveraging Biomarkers and Diagnostics to Accelerate Drug Development *30*
2.4.4.2 Potential to Enhance Commercial Success with Companion Diagnostics *32*
2.4.5 Personalized Medicine *33*
2.5 Case Scenario *33*
2.6 Timeline *34*
2.7 Study Plan and Assignments *34*
2.7.1 Session 1 *34*
2.7.2 Session 2 *35*
2.7.3 Session 3 *35*
2.7.4 Session 4 *36*
2.7.5 Session 5 *39*
2.7.6 Session 6 *39*
Acknowledgment *39*
Resources *39*

3 Product Portfolio Planning and Management in the Pharmaceutical Industry *41*
Alan Woodall

3.1 Mission *42*
3.2 Goals *42*
3.3 Predicted Learning Outcomes *43*
3.4 Introduction *43*
Preclinical Phase *44*
Phase I *44*
Phase II *44*
Phase III *44*
Marketing Application *44*
Phase IV *44*
3.5 Case Scenario *46*
3.6 Timeline *47*
3.7 Study Plan and Assignments *47*
3.7.1 Session 1 *47*
3.7.2 Session 2 *49*
3.7.3 Session 3 *51*
3.7.4 Session 4 *52*
3.7.5 Session 5 *55*
3.7.6 Session 6 *55*
3.7.7 Session 7 *55*
3.7.8 Session 8 *55*
Appendix A: Method for Net Present Value Calculations *58*
Appendix B: Glossary of Abbreviations and Terms *59*

4 Entrepreneurship: Establishing a New Biotechnology Venture *61*
Cedric Pearce

4.1 Mission *62*
4.2 Goals *62*
4.3 Predicted Learning Outcomes *62*
4.4 Introduction *62*
4.4.1 Characteristics of an Entrepreneur *63*
4.4.2 Twenty Questions to Determine How Entrepreneurial You Are *64*
4.4.3 *From Idea to Concept Evaluation* *65*
4.4.4 Assessing Opportunity and Writing a Business Plan *68*
4.4.5 Organizing the Venture *71*
4.4.6 Financing the Business *72*
4.4.7 Start-Up Dynamics *74*
4.5 Timeline *75*
4.6 Study Plan and Assignments *75*
4.6.1 Session 1 *75*
4.6.2 Session 2 *76*

此为试读,需要完整PDF请访问: www.ertongbook.com

4.6.3 Session 3 *76*
4.6.4 Session 4 *76*
4.6.5 Session 5 *77*
4.6.6 Session 6 *77*
4.6.7 Session 7 *77*
4.6.8 Session 8 *77*
Resources *78*

5 Introduction to US Patent Law *79*
Elaine T. Sale

5.1 Mission *80*
5.2 Goals *80*
5.3 Predicted Learning Outcomes *80*
5.4 Introduction *81*
5.4.1 Brief Description of US Patents *81*
5.4.2 Patentable Subject Matter *83*
5.4.3 Utility *84*
5.4.4 Novelty *85*
5.4.5 Nonobviousness *88*
5.4.6 Enablement *90*
5.4.7 Written Description *91*
5.4.8 Best Mode *92*
5.4.9 Claim Drafting *92*
5.4.10 Invention and Inventorship *96*
5.4.11 The Patent Process: Obtaining and Maintaining a Patent *99*
5.4.12 Patent Infringement *106*
5.4.13 Patent Ownership and Intellectual Property Agreements *110*
5.5 Timeline *113*
5.6 Study Plan and Assignments *113*
5.6.1 Session 1 *113*
5.6.2 Session 2 *113*
5.6.3 Session 3 *113*
5.6.4 Session 4 *114*
5.6.5 Session 5 *114*
5.6.6 Session 6 *114*
5.6.7 Session 7 *114*
5.6.8 Session 8 *115*
Resources *115*

6 Intellectual Property Management *117*
William Barrett

6.1 Mission *118*
6.2 Goals *118*
6.3 Predicted Learning Outcomes *119*

6.4 Introduction *119*
6.4.1 Economics of IP *120*
6.4.2 Globalization of Innovation *121*
6.4.3 Creating an IP Strategy *122*
6.4.3.1 IP Vision *123*
6.4.3.2 IP Plan *124*
6.4.3.3 IP Team *124*
6.4.4 Invention Assessment *125*
6.4.4.1 Novelty *125*
6.4.4.2 Probability of Technological Success (Technology Risk) *126*
6.4.4.3 Invention Type *126*
6.4.5 Mapping the Competitive Patent Landscape *127*
6.4.5.1 Conducting a Search *128*
6.4.5.2 Identification of Relevant Patent Documents *129*
6.4.5.3 Mapping of Relevant Patent Documents *129*
6.4.5.4 Screening Out Clearly Noninfringing Patents *132*
6.4.5.5 Analyzing Potentially Infringing Patents *132*
6.4.5.6 Analyzing Clearly Infringing Patents *134*
6.4.6 Conclusion *135*
6.5 Timeline *135*
6.6 Study Plan and Assignments *135*
6.6.1 Session 1 *135*
6.6.2 Session 2 *136*
6.6.3 Session 3 *137*
6.6.4 Session 4 *138*
6.6.5 Session 5 *139*
6.6.6 Session 6 *140*
6.6.7 Session 7 *140*
6.6.8 Session 8 *140*

7 Operational Excellence in Pharmaceutical Manufacturing *141*
Lucia Clontz

7.1 Mission *143*
7.2 Goals *143*
7.3 Introduction *143*
7.3.1 Overview of the Drug Manufacturing Process *143*
7.3.2 A Change in Paradigm for the Pharmaceutical Industry *144*
7.4 Part I – Operational Excellence: Implementing Process Improvements *145*
7.4.1 Introduction to Lean Manufacturing *145*
7.5 Predicted Learning Outcomes *148*
7.6 Case Scenario *149*
7.7 Timeline *149*
7.8 Study Plan and Assignments *150*

7.8.1 Session 1 *150*
7.8.2 Session 2 *151*
7.8.3 Session 3 *153*
7.8.4 Session 4 *154*
7.8.5 Session 5 *154*
7.8.6 Session 6 *156*
7.8.7 Session 7 *156*
7.8.8 Session 8 *157*
7.9 Company Supervised Practicum *157*
7.10 Part II – Optimizing Existing Technologies *161*
7.10.1 Introduction to Quality Control *161*
7.11 Predicted Learning Outcomes *161*
7.12 Case Scenario *162*
7.13 Timeline *163*
7.14 Study Plan and Assignments *163*
7.14.1 Session 1 *163*
7.14.2 Session 2 *164*
7.14.3 Session 3 *165*
7.14.4 Session 4 *166*
7.14.5 Session 5 *167*
7.14.6 Session 6 *168*
7.14.7 Session 7 *168*
7.14.8 Session 8 *168*
7.15 Company Supervised Practicum *169*
7.16 Conclusion *173*

8 Aligning Behaviors and Standards in a Regulated Industry: Design and Implementation of a Job Observation Program *175*
Amy Peterson and John Shaeffer

8.1 Mission *176*
8.2 Goals *176*
8.3 Predicted Learning Outcome *177*
8.4 Introduction *177*
8.4.1 Human Error and Human Error Prevention by Job Observation *177*
8.4.2 Procedural Adherence and Human Behavior *178*
8.4.3 The Necessity for Job Observation *178*
8.5 Case Scenario *179*
8.6 Timeline *181*
8.7 Study Plan and Assignments *181*
8.7.1 Session 1 *181*
8.7.1.1 Assignment #1 *181*
8.7.2 Session 2 *181*
8.7.2.1 Presentations *181*

8.7.2.2 Assignment #2 *181*
8.7.3 Session 3 *182*
8.7.3.1 Assignment #3 *182*
8.7.4 Session 4 *182*
8.7.4.1 Assignment #4 *182*
8.7.5 Session 5 *182*
8.7.5.1 Assignment #5 *182*
8.7.6 Session 6 *182*
8.7.6.1 Assignment #6 *182*
8.7.7 Session 7 *182*
8.7.7.1 Assignment #7 *182*
8.7.8 Session 8 *183*
8.7.8.1 Presentations *183*
8.8 Items Needed for a Widely Applicable Job Observation Program *183*
8.9 Job Observation Program Evaluation *184*
Appendix A: Job Observation Program for a Commercial Kitchen *184*
A1 Behavior Standards *185*
A2 Metrics *185*
A3 Example Form: Job Observation – Commercial Cooking *186*
A4 Items for the basis of an observation program *187*
Appendix B: Job Observation Program for GMP Documentation in a Manufacturing Facility *190*
B1 Behavior Standards *190*
B2 Metrics *190*
B3 Example Form: Job Observation for GMP Documentation in a Manufacturing Facility *191*
B4 Comparison: Manufacturing Observation Program vs. Standards *191*
B4.1 Items for the basis of an observation program *191*
Appendix C: Test *195*
Test and Test Answers *195*
Resources *196*

Subject Index *197*

1
Principles of Industry Immersion Learning

Lisbeth Borbye

Contents

1.1 Introduction *2*
1.2 Building a University – Industry Alliance *3*
1.2.1 Educational Needs Assessment *3*
1.2.2 Establishing Contact *3*
1.2.3 Marketing Incentives *5*
1.2.4 Obtaining Commitment *5*
1.2.5 Alliance Dynamics *5*
1.3 Design, Format, and Model Examples of Case Studies *6*
1.3.1 Example 1: Technology Development *6*
1.3.2 Example 2: Product Assessment *7*
1.3.3 Example 3: Business Development *7*
1.4 Basics of Industry Immersion Learning *8*
1.4.1 Definition and Characterization *8*
1.4.2 The Immersion Environment *8*
1.4.3 Sample Work Flow of an Immersion Case Study *8*
1.4.4 Interactive Agents *8*
1.5 Predicted Learning Outcomes *9*
1.6 Assessment of Actual Learning Outcomes *10*
1.7 Overview of Selected Case Studies *10*
1.8 Logistics of Industry Immersion Teaching *11*
1.8.1 Topic Selection *11*
1.8.2 Instructor and Instructor Affiliation *11*
1.8.3 Timeline *13*
1.8.4 Location *13*
1.8.5 Teaching Format *14*
1.8.6 Student Deliverables *14*
1.8.7 Legal Requirements *15*
1.9 Publishing of Industry Immersion Case Studies *15*

Industry Immersion Learning. Real-Life Industry Case-Studies in Biotechnology and Business
L. Borbye, M. Stocum, A. Woodall, C. Pearce, E. Sale, W. Barrett, L. Clontz, A. Peterson, J. Shaeffer
Copyright © 2009 WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim
ISBN: 978-3-527-32408-8

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 learn-

此为试读,需要完整PDF请访问: www.ertongbook.com