#### Sabbatical Report 2015-2016

### Subhash B. Karkare, Ph.D.

#### Professor of Biotechnology, Moorpark College

#### Background

This report summarizes the activities and accomplishments during my sabbatical leave (Spring 2016). The purpose of the sabbatical leave was to completely revise and update the textbook (Industrial Biotechnology: A Training Manual - ISBN-7593-0514-5) that was originally published by Moorpark College in 2001. The content of the book has never been revised since its original publication in 2001. There have been many advancements in Industrial Biotechnology since the publication of this book. Therefore, it was my intention to completely revise and update this excellent text book so that students of Industrial Biotechnology have a concise, yet comprehensive resource to go to for practical knowledge of this important field. The intent was to bring the content of the book up to date with current state of the art in this industry and to introduce new technologies that have become part of this field since the original publication of the book in 2001.

#### Summary of accomplishments and activities

During my sabbatical I conducted the following activities

- Organized the book into a completely new structure with sections to parallel the courses being offered at Moorpark College. This included an introductory section called "Core Concepts", four sections corresponding to four of the courses offered by Moorpark (Environmental Monitoring & Process Support, Quality control & Validation, Cell Culture & Microbial Fermentation, Recovery & Purification) and a final section called "Analytical Methods" which was to include analytical methods used in all other courses.
- The book was organized in six sections with a total of 49 chapters.
- Identified a group of industry experts willing to help with revising/writing chapters for the book that were outside my areas of expertise.
- Conducted face to face meetings with these industry experts to provide them with guidance on the writing of their topics.
- Researched topics for the "Cell culture and microbial fermentation" section (which was to be written by me) as well as many other topics that I could not find industry experts for.
- Wrote (or substantially revised from the previous textbook) all the chapters of the "Cell Culture and Microbial Fermentation" section and those other

chapters that I could not find external authors for. In all, I wrote 24 of the 49 chapters in the book. I am currently in the process of writing 2 more chapters that had originally been assigned to other authors. This will bring my authorship to 26 of the 49 chapters.

- Followed up with other contributors via phone calls, emails, and face to face meetings to keep the project on track for completion. This was a difficult process since most of these contributors have full time jobs in the industry and have to write the chapters in their spare time (with no compensation).
- By the end of the sabbatical period I was able to complete 47 of the 49 chapters of the book. Of these 49 chapters:
  - 26 are authored by me (24 of which have been completed)
  - 15 were authored by other industry experts
  - 8 chapters were essentially the same as the original textbook with editorial changes made by me.
- Appendix I shows the table of contents of the new book including the authors for various chapters.
- Although I intended to have the book published by the end of the sabbatical period, the publication itself could not be completed due to several extenuating circumstances:
  - The Moorpark Biotechnology Program was selected as a finalist for the Bellwether Award. This necessitated me to spend substantial time preparing for a presentation and then travelling to Florida to make the presentation.
  - I planned, organized and conducted the annual meeting of our Biotechnology Advisory Committee.
  - I attended the annual CSUPERB (California State University Program for Education and Research in Biotechnology) conference in January
  - I attended a meeting organized by the DSN for Biotechnology in Miramar College to discuss best practices in Biotechnology education.
  - Some of the industry experts who had committed to write chapters for the book did not follow through on their commitment despite my best efforts to follow up with them. This necessitated me to write more chapters myself (including doing the research for those chapters.)
- Work that still remains to be done (which I intend to complete this summer on my own time) is as follows:
  - I will do the bulk of editorial work to make sure that all disparate chapters are well linked and are presented in a coherent manner.
  - I will obtain consent from original publishers of work cited
  - I will correspond with publisher to get the book in its final form

# Appendix I

## **Table of Contents**

Section	Торіс	Author	Chapter
Core Concepts	Biotechnology Process	Subhash Karkare	1
	Overview		
	Good Manufacturing Practices	Subhash Karkare	2
	Overview		
Environmental	Facility Layout and	Tim Grasel	3
Monitoring and	Environmental Controls		
Process Support	Clean Rooms and Gowning	Amgen*	4
	Practices		
	Environmental Monitoring	Stephanie Ramsey	5
	Laser Particle Counters	Amgen*	6
	Cleaning of Equipment and Containers	Subhash Karkare	7
	Sterilization of Equipment and Containers	Subhash Karkare	8
	Equipment and Sanitary Design	Subhash Karkare	9
	Buffer and Media Batching	Colonia Wong,	10
		Tharmala	
		Tharmalingam	
	Control Systems	Steven Seltzer*	11
Quality Control and	The Quality Unit: QA and QC	Subhash Karkare	12
Validation	Good Documentation Practices	Amgen*	13
	Deviation Investigations	Lisa Severy	14
	Introduction to Validation	Subhash Karkare	15
	Computer Validation	Subhash Karkare	16
	Equipment Qualification	Subhash Karkare	17
	Raw Material Qualification and Testing	Subhash Karkare	18
	Process Validation and Characterization	Tim Grasel	19
	Cleaning Validation	Subhash Karkare	20
	Transportation Validation	Subhash Karkare	21
	Analytical Method Validation	Subhash Karkare	22
	Continuous Process Monitoring	John Haury, Michelle Kobrin*	23
	Six Sigma and Lean Manufacturing	Subhash Karkare	24
	Batch Record Review and Lot	Subhash Karkare	25
	Release		

Microbial	Technology		
Fermentation	Cell Biology	Subhash Karkare	27
	Microbial Overview	Subhash Karkare	28
	Clean Room conduct and	Subhash Karkare	29
	Aseptic Technique		
	Mammalian Cell Culture	Subhash Karkare	30
	Single use Bioprocessing	Subhash Karkare	31
	Biofuels	Subhash Karkare	32
	Microbial Fermentation	Subhash Karkare	33
Recovery,	Protein Chemistry and Structure	Subhash Karkare	34
Purification, and	Overview of Protein Recovery	John Ogez*	35
Formulation	Cell Disruption	Darrell Lewis-Sandy,	36
		Chris Rosenfeldt, John	
		Ogez, Mark Byers,	
		Maria Caicedo, Adrian	
		Distler, Michelle	
		Dowling, Bill Entrup*	
	Centrifugation	Timothy Grasel	37
	Chromatography	Daphne Feng, Oliver	38
		Kaltenbrunner, Mike	
		Mills, John Ogez, Bob	
		Seely, Ali Siahpush,	
		Peter Watler*	
	Tangential Flow Filtration	Subhash Karkare	39
	Normal Flow and Sterile	Subhash Karkare	40
	Filtration		
	Protein Formulation-Fill-Finish	Tim Grasel	41
	Operations		
Analytical Methods	pH and DO Detection	Tharmala	42
in Biotech		Tharmalingam	
Manufacturing	Cell Enumeration	Tharmala	43
		Tharmalingam	
	Mycoplasma Detection	Mary Rees	44
	ELISA	Tharmala	45
		Tharmalingam	
	LAL and Microbial Analysis	Tharmala	46
		Tharmalingam	
	High Pressure Liquid	Tharmala	47
	Chromatography	Tharmalingam	
	Electrophoretic Methods	Tharmala	48
		Tharmalingam	
	Stability Testing	Melissa Kirkegaard	49
		and Everyll Swanson	

\*As originally written with editorial changes only