Professional Portfolio

Jignesh Padia
MSc Biochemical Engineer

PROFESSIONAL OBJECTIVE

A position in biopharmaceutical industry with a combined technical and business leadership role where my unique combination of skills and experience can be of mutual benefit. I wish to utilize my qualifications and expertise in ***facility design***, ***fermentation*** *and* ***downstream processing*** *as a process engineer or technical consultant.*

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Section A
Education Details

Summary

2002 - 2003: University College London, United Kingdom
MSc Biochemical Engineering *(Distinction)*

I have completed my masters in Biochemical Engineering from University College London (UCL). At UCL I had an opportunity to work in Advanced Biochemical Engineering Center (ABEC), which involved several pilot scale equipments i.e. Fermenters, High pressure Homogenizer, Disc-stack & Tubular-Bowl Centrifuges and Chromatography columns etc. I gained hands on experience on bioprocess unit-operations understanding the need of process integration and scale-down concepts.

My design project was on development of Monoclonal Antibodies (MAbs) at large scale using CHO cell line. This project was assessed by members from industrial panels, which included George Blewett from ***Jacobs Engineering*** *& Other leading process engineers from* ***Lilly*** *and* ***Pfizer*** *etc. I successfully completed my course by securing 3rd rank and distinction.*

Course Modules

- *Process Validation & Scale-up*
- *Fermentation Operations*
- *Downstream Process Design*
- *Mass Transfer and Fluid Mechanics*
- *Advanced Bioreactor Design*
- *Chemical Engineering Principles*

1999 - 2002: Saurashtra University (Christ College), Gujarat, India
BSc. Microbiology *(First Class)*

I completed my BSc in Microbiology from Christ College, Saurashtra University. This three year course was mix of practical and theory on chemistry, physics and biology with specialization in Microbiology during 2nd & 3rd Year. Here, I had an opportunity to learn the fundamentals of microbiology, microbial & protein biochemistry, immunology as well as industrial microbiology.

UNIVERSITY OF LONDON

University College London

Jignesh Padia

having completed the approved course of study and passed the examinations has this day been admitted by University College London to the University of London Degree of

MASTER OF SCIENCE

with Distinction
in Biochemical Engineering

Provost and President, University College London

Vice-Chancellor

1 November 2003

UNIVERSITY COLLEGE LONDON

(UNIVERSITY OF LONDON)
Gower Street, London WC1E 6BT

Student: Jignesh PADIA

Date Of Birth: 14 November 1981

Title of Programme at time of leaving : M.Sc. in BIOCHEMICAL ENGINEERING

Date of First Enrolment: 23 September 2002 **Date of Leaving:** 15 September 2003

Qualification Awarded: M.Sc. (Distinction)
Date of award: 01 November 2003
Field in which awarded: BIOCHEMICAL ENGINEERING

The programme consisted of the following courses:	Credit Value	Mark	Result
Academic Year 2002–2003			
Biochem Eng G15: Dissertation on Bioprocess Design	40.00	66	Pass
Biochem Eng G19: Bioprocess Synthesis and Process Mapping	10.00	80	Distinctn
Biochem Eng G20: Bioprocess Engineering Design and Regulatory Constraints	10.00	77	Distinctn
Biochem Eng G21: Mass, Heat and Momentum Transfer and Bioprocess Material Properties	10.00	82	Distinctn
Biochem Eng G22: Advanced Bioreactor Engineering	10.00	60	Pass
Biochem Eng G23: Integrated Downstream Processing	10.00	82	Distinctn
Biochem Eng G24: Integrated Biochemical Engineering Design	10.00	67	Pass
Biochem Eng G25: Bioprocess Management - Discovery to Manufacture	10.00	66	Pass
Biochem Eng G26: Bioprocess Entrepreneurial Business Plan	10.00	63	Pass
OVERALL FINAL MARK	0.00	70	Distinctn

Value of Credits satisfactorily completed : - 120.00 out of 120.00
********* End of Transcript *********

Section B

Resume

PERSONAL DETAILS

Address: *Flat 1/1, 30 Reidvale Street, Glasgow, Scotland - G311SZ*
Email: *jignesh_padia@yahoo.com*
Telephone: *0141 5501213*

PROFESSIONAL OBJECTIVE

A position in biopharmaceutical industry with a combined technical and business leadership role where my unique combination of skills and experience can be of mutual benefit. I wish to utilize my qualifications and expertise in facility design and downstream processing as a process engineer or technical consultant.

KEY SKILLS (Technical):

** Facility Design* ** Process Design & Simulation* ** CMO – Setup & Technology Transfer*
** Project Management* ** Quality Assurance (Validation & cGMP)*

EDUCATION

2002 - 2003: University College London, United Kingdom
MSc Biochemical Engineering *(Distinction)*

1999 - 2002: Saurashtra University (Christ College), Gujarat, India
BSc. Microbiology *(First Class)*

WORK EXPERIENCE

June 2005 – Present: QSV Biologics Ltd. (Canada)

Interim Project Manager (3 months)

- *Managed techno-commercial aspects of contract manufacturing for our clients.*
    - *Defining Scope, Resource allocation, Cost analysis, Project timelines and Process design activities.*
    - *Setup of Process Development Labs, Systems and Recruitment activities*
    - *Created process simulation packages for internal usage (i.e. Facility Design, Suite Occupancy, Process Scale-up etc)*

Process / Projects Consultant (1.5 years)

- *Technical Lead of Facility design project for 10,000L multi-product, multi- client facility*
- *Lead on Technology Selection and Process Consultation for the Biotech Projects*
- *Facilitated Technology Transfer of GMP manufacturing processes for clinical trials and Phase I, II, III studies.*
- *Responsible for reviewing tech-transfer documents*
- *Technical Support to manufacturing group for scale-up and engineering runs.*
- *Troubleshooting of development and manufacturing processes.*

Process Development Associate / Process Engineer (3 years)

- *As a part of tech-transfers / engineering runs, gained experience on Large-scale fermentors, NCSRT Filtration system, Large-Scale Bioprocess Chromatography system, BPG columns, Pellicon Maxi – CUF system and other associated DSP equipments.*
- *Responsible for development and scale-up of processes for biologics and biotherapeutic proteins.*

WORK EXPERIENCE – Cont.

July 2004 - March 2005: Millipore (India) Pvt. Ltd.

Process Development Scientist (1 year)

- *Responsible for techno-commercial aspects of filtration & chromatography unit operations*
- *Process Development & Process optimisation of DSP for biologics: System sizing, Scale-down experiments, System Installation & Validation documentation*
- *Training Clients – Millipore Tech School Programme*
- *Developed skills in business management, presentation, filtration and chromatography process validation & operations.*

November 2003 - July 2004: Cadila Pharmaceuticals (India)

Process Development Scientist (Biotech Internship / Training - 6 months)

- *Responsible for process development aspects of recombinant EPO & recombinant Insulin*
- *Experienced handling mammalian cell culture, bacterial cell, protein purification and documentation.*

PUBLICATION

2006

- *"Integrated Process Design & Development" – Bioprocessing Tutorial*, ***Genetic Engineering News***
- *"**Gas filtration:** sterile micro-filtration for bioreactors",* ***Filtration & Separation***

2005

- *"The Feasibility Of Tangential Flow Filtration For Cell Lysate Clarification",* ***Biopharm International***

2002

- *Research project on "Biodiversity and Enzymatic Potential of Thermophiles" at 43rd Annual Conference of Association of Microbiologists of India.*

PRESENTATION

2007

- *"Process Development of Biotherapeutics" – at AIF(Alberta Ingenuity Fund) networking event*
- *"Managing manufacturing aspects in biotechnology" – annual presentation to internal QSV team*

2006

- *"Filtration – as a part of downstream process" – to internal QSV team (training seminar)*

2005

- *" How to operate AKTA 100 Air" presentation to internal QSV team (training seminar)*

REFERENCES

Please see the references section

Section C
Technical & Soft Skills

IT Skills

- *Can perform various types of system installation and application installation and upgrades on WINDOWS based systems. Very little experience with Unix or any other OS*
- *Microsoft Excel*
    - *Ability grasp complex ideas and to design spreadsheets with multiple interdependency.*
    - *Created simulation using XL for facility/plant utilization*
    - *Created simulation using XL for process scale-up*
    - *Created simulation using XL for Facility Design and Cost related sensitivity aspects*
- *MS Project*

Project management

- *Worked on multiple projects in a CMO (Contract Manufacturing Organization)*
- *Professional training by IChemE: Project Management module (Online)*
- *Defining Scope, Resource allocation, Cost analysis, Project timelines and Process design activities.*
- *Setup of Process Development Labs, Systems and Recruitment activities*

Training, presentations, providing advice on system configuration, integration and system usage

- *Technical presentation to clients as a process engineer (Millipore Consultant)*
- *Technical presentation to clients as a project manager (QSV Biologics)*
- *Provided technical training to Millipore clients as a part of Millipore filtration school.*
- *Technical consultant to clients for new projects*
- *Consultant role in setup activities of a process development lab*

Sales support on technical aspects (Client interface).

- *Sales support to Millipore's sales team*
- *Sales support to QSV's projects team*

GLP/GMP experience

- *Worked in a GLP and GMP environment*
- *Familiar with the process validation scope.*
- *Awareness on computer and software validation*

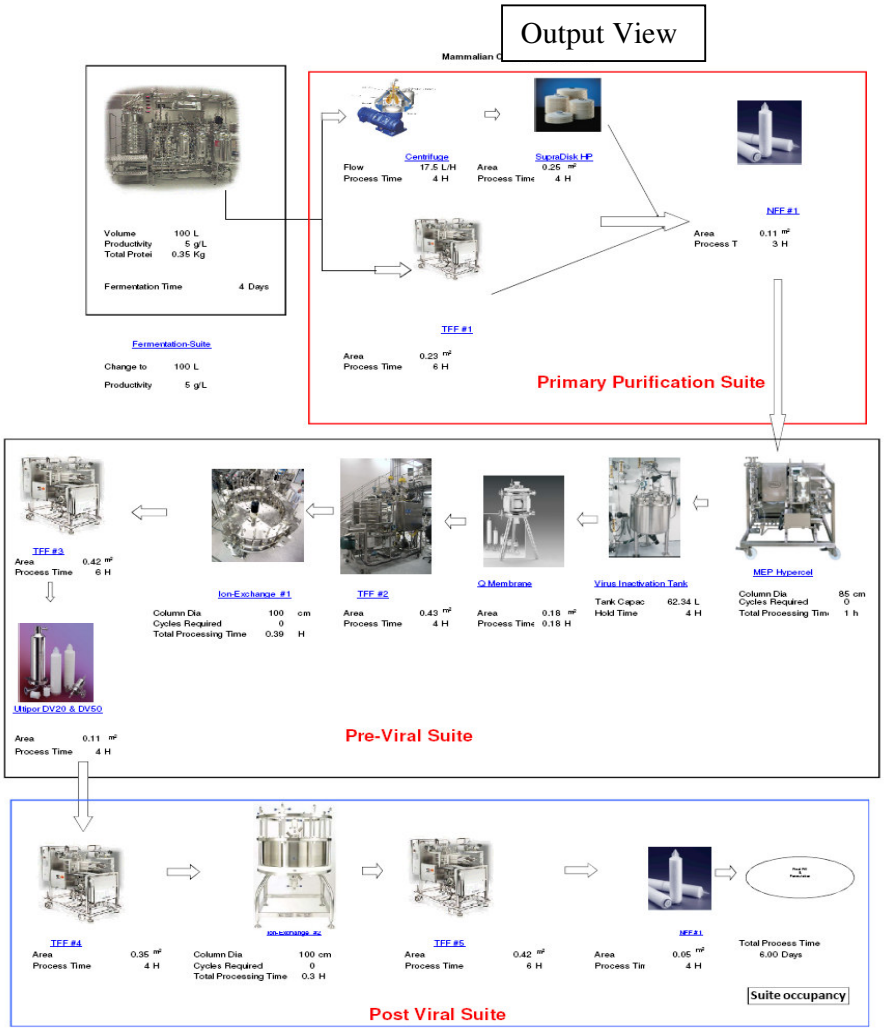
Example of Facility Design Simulation:

Objectives/Scope:

1. *To allow user to simulate the plant operations based on the fermentation scale and productivity.*
2. *Allow user to estimate the requirements for the desired unit-operations. This requires user to feed in the minimum operation requirements.*
3. *To predict the processing time of each unit-operation*
4. *To predict the mass balance in each stream and unit-operation*
5. *Allows user to quickly compare the outcome by changing one or multiple parameters.*

Application *(Industry utilizing unit operations, i.e. Filtration, Chromatography, Centrifuge)*

1. *Pharmaceutical Industry*
2. *Biotech Industry*
3. *Chemical or any other Process industry*



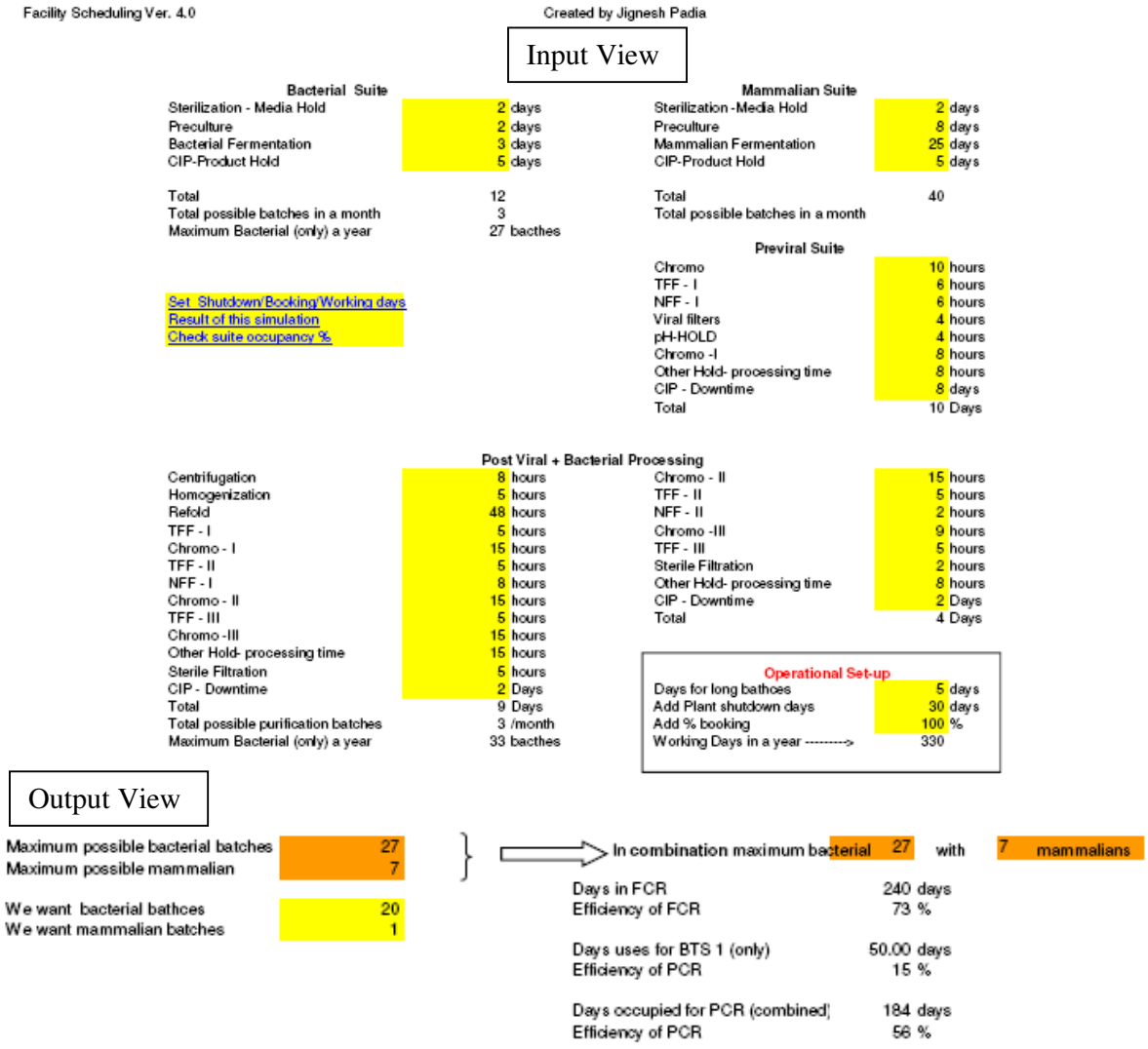
Example of Manufacturing Suite Scheduling:

Objectives/Scope:

1. *To allow user to simulate the plant occupancy based on the unit-operation.*
2. *Allow user to estimate the number of possible batches based in a year on the time required for the desired unit-operations. This requires user to feed in the minimum operation requirements.*
3. *To predict the possible output of batches per month and per annum.*
4. *To predict the bottle neck when working with several clean rooms and suites.*
5. *Allows user to quickly compare the outcome by changing one or multiple parameters.*

Application *(Industry utilizing unit operations, i.e. Filtration, Chromatography, Centrifuge)*

1. *Pharmaceutical Industry*
2. *Biotech Industry*
3. *Chemical or any other Process industry*



Section D
Abstract of Publications

2006 Genetic Engineering News: Tutorial - Bioprocessing
"Integrated Process Design & Development"
Finding the Optimal Window of Operation and Steering Clear of Bottlenecks

Abstract
Process development and integration of unit operations during the drug development cycle for a typical microbial or mammalian cell culture process is important. Most biopharmaceutical companies have their own in-house process development programs. In addition, several CMOs are involved in process development and the production of material for preclinical, Phase I–III, or even GMP manufacturing.

Despite all of this, there is often a lack of vision, especially from small research companies, for process development, resulting in non scalable and highly expensive processes. Developing a scalable, robust, and regulatory-compliant process requires time, sophisticated equipment, skilled scientists and engineers, and, above all, money (Figure 1). Process development can only be justified if the developed process is scalable, cost-effective, and can be validated. Integration and selection of unit-operations from the research phase is of prime importance and making the right decisions early on can definitely save time and money in the later stages of product development.

- *Integration of Discovery-Development Phase*
- *Integration of Process Development Operations*

2006 - Filtration & Separation
"Gas filtration: sterile micro-filtration for bioreactors"
Sterilising gas filters- a valuable and indispensable part of modern biotech and pharmaceutical processes

Abstract
Pharmaceuticals, biotechnology, and healthcare are high growth segments for the filter market due to the broad growth of aseptic and sterile processing. The present cartridge filter market is about US$2 billion per year with a projected growth rate of 9 percent. This article is focused on the sterile filtration of gases used for the fermentation process and fermenter/tank vent applications.

- *Filter applications for bioreactors and sterile vessels*
- *Cartridge filter construction*
- *Hydrophobic filter removal ratings*
- *Filter sizing*
- *Filter housings*
- *Integrity test methods for hydrophobic filters*
    - *Bubble point*
    - *Pressure decay/Pressure hold*
    - *Water intrusion test (WIT)*
- *Sterilise in place(SIP)*
- *Clean in place (CIP)*

2005 - Biopharm International

"The Feasibility Of Tangential Flow Filtration For Cell Lysate Clarification", Biopharm International

Abstract

Tangential flow filtration (TFF) is an efficient and unavoidable downstream processing (DSP) method for the clarification and purification of biologics. Membrane filtration is a solid – liquid separation technique that has been widely used in the biotech industry for many years. Depending on membrane porosity, it can be classified as a microfiltration or ultra filtration process. Microfiltration membranes have pore sizes typically between 0.1 µm and 10 µm. Ultrafiltration membranes have much smaller pore sizes and are classified based on cutoff, which is based on their ability to retain the protein with a known molecular weight. A rule of thumb is to select the three- to five-times smaller membrane cutoff than the molecular weight of the protein to be retained. TFF is commonly used for concentration, desalting, buffer exchange, and fractionation of proteins. Until recent years there were limited applications of TFF in cell harvest and cell lysate clarification. This case study describes the possible use of TFF as an alternative to centrifugation for cell harvest and cell lysate process.

Future Goals

I wish to publish more articles in the area of process integration, process design and projects management by gaining more experience in facility design/operations, technology transfer and project management. I wish to share the challenges of CMO operations and potential solutions for those challenges by focusing on Scale-up, Quality, Regulatory requirements and Speed to market.

Section E

Professional Training

&

Memberships

Professional Training

2008 (Laporte Consultants)

- *Manufacturing Training Programme – Fermentation / Cell culture operations*
  - *Fermentation & Cell Culture Principles*
  - *Bioreactors and Process Control & Operations*
    - *CIP, Setup, SIP, Inoculation, Operation & Harvest*
- *Manufacturing Training Programme – Primary recovery*
  - *Harvest Unit-Operations*
  - *Cell Disruption & Refolding Operations*
    - *CIP, SIP, Setup, Operation & Troubleshooting*

- *Manufacturing Training Programme – Purification / Downstream Processing*
  - *TFF & Chromatography Operations*
    - *CIP, SIP, Setup, Operation & Troubleshooting*

2007

- *Novel resins For Process Improvement (Pall – Training Seminar)*
  - *Appropriate Chromatographic Method for a Specific Application*
  - *Mixed-mode Chromatography*
  - *Membrane Adsorbers as a Tool for Rapid Purification*

- *Optimization Of Tangential Flow Filters (Millipore – Training Seminar)*
  - *Membrane Selection*
  - *Optimizing TFF Operation*
  - *Improving Process Yields*

- *Selection Of Microfluidizer For Cell Rupture Process (Microfluidics- Seminar)*
  - *Technology Understanding*
  - *Process Capabilities & Limitations*

2006

- *IChemE (continuous learning modules)*
  - *Project Management Principles*

2006

- *ASME Bioprocess Seminars – Bioprocess purification process*

Basic Concepts in Chromatography
A discussion of chromatographic techniques, nomenclature, & metrics used in process development.
Alan Williams
Applications Manager
GE Healthcare

Refreshment Break w/ Exhibitors

Critical Aspects of Chromatographic Process Design
A discussion of how to design a scalable & robust multi-step purification strategy.
Alan Williams
Applications Manager
GE Healthcare

Lunch w/ Exhibitors

Process Design I: Membrane Process
A review of the critical aspects of membrane system process design & integration with chromatography processes.
Yujing Yang
Technical Director, Membrane Marketing
GE Healthcare

Process Design I: Membrane Process (continued)
A review of the critical aspects of membrane system process design and integration with Chromatography processes
Yujing Yang
Technical Director, Membrane Marketing
GE Healthcare

Wednesday, October 25, 2006

Registration Desk Open / Continental Breakfast w/ Exhibitors

Scale Down Modeling and Determination of Media Lifetime
Current models and approaches to determine media lifetime in chromatographic and filtration processes.
Anurag Rathore
Process Development
AMGEN Inc.

Refreshment Break w/ Exhibitors

Scale Down Modeling and Determination of Media Lifetime Continued
Current models and approaches to determine media lifetime in chromatographic and filtration processes.
Anurag Rathore
Process Development
AMGEN Inc.

Lunch w/ Exhibitors

Production Scenario I: Antibody Production Process
A look at a mammalian cell process making antibody at the 100-g level.
Tamas Blandl
Scientist, Process Development
AMGEN Inc.

Refreshment Break w/ Exhibitors

Production Scenario I: Antibody Production Process Continued
A look at a mammalian cell process making antibody at the 100-g level.
Tamas Blandl
Scientist, Process Development
AMGEN Inc.

Thursday, October 26, 2006

Registration Desk Open / Continental Breakfast

Process Design II
Optimizing and maintaining the process.
Tim Breece
Development Engineer
Genentech

Refreshment Break

Process Design II
Continued optimizing & maintaining the process; a continuation of Process Design I (automation, etc.)
Tim Breece
Development Engineer
Genentech

Lunch

Validation in the Plant
An overview of validation in the plant with an emphasis on protein purification by chromatography.
Lisa Gonzales
Sr. Reg. Compliance Specialist
GE Healthcare

Refreshment Break

Industrial Scale Column Packing
Discussion of column packing techniques, the critical aspects of good column packing, and its effects on production.
Alan Williams
Applications Manager
GE Healthcare

PLANT TOUR: BRI Bioprocess Plant - 50 Maximum

- *Trends in Protein Purification (GE – Seminar/Training Programme)*
    - *Modes of Chromatography*
    - *Resin & System Selection*
    - *Process Examples & Troubleshooting*

Professional Memberships

- *Associate Member – IChemE*
    - *BESG – Subject Group Member*
- *Affiliate Member – ASME*
- *Affiliate Member - The European Federation of Biotechnology*
- *Affiliate Member – PDA*

I wish to continue my professional growth by being active member of professional bodies associated with biopharmaceutical industries. I aspire to gain a Chartered Chemical Engineer (C.Eng) Status offered by IChemE. I also aim to secure professional status of Certified Pharmaceutical Industry Professional (CPIP)

Section F
Awards & Achievements

Academic Achievements

2004

- ***First prize*** *in Science Symposium for oral presentation: "**Downstream Processing of Plasmid DNA**"*

2003

- *Awarded with Andrew Stratton Bursary 2003/4 for higher education.*

2002

- *Awarded **Gold Medal** and **J.M. Dave Award** for outstanding performance in **BSc Microbiology**.*
- ***Ranked 1st** in College (and overall 2nd in University) in Final year of B.Sc. Microbiology.*

Professional Achievements

2007

- *Successful completion of PD projects **Tech Transfer** to GMP suites*
- *Presentation - "Process Development of Biotherapeutics" – at AIF(Alberta Ingenuity Fund) networking event*
- *"Managing manufacturing aspects in biotechnology" – Annual presentation to internal QSV team*

2006

- *Awarded professional status of **Associate Membership** by IChemE*
- *Awarded **Alberta Ingenuity Award** for engineers by Alberta government.*
- *Successful completion of Conceptual Facility Design Project for multi-product, multi-client facility*
- *"Filtration – as a part of downstream process" – to internal QSV team (training seminar)*

2005

- *Awarded **Alberta Ingenuity Award** for engineers by Alberta government.*
- *" How to operate AKTA 100 Air" presentation to internal QSV team (training seminar)*

2004

- ***Award** for outstanding performance for the **Validation studies** and to meet the strict project deadline given by **Millipore**.*

Section G
References

Quality and Speed build Value

February 12, 2008

Re: Letter of recommendation for Mr. Jignesh Padia

It is my great pleasure to recommend Mr. Jignesh Padia in support of his IChemE chartered chemical engineer application. I have a PhD in biotechnology and have more than 15 years of experience in process development of biologics for clinical and commercial production.

QSV biologics employed Mr. Jignesh Padia as a process development associate in June 2005. Since then Jignesh has worked on seven different process development projects involving different Genetically Modified Organisms (GMOs) (i.e. *E. coli*, *Pichia pastoris*, *Saccharomyces cerevisiae*). I have evaluated Jignesh's progress at QSV in my capacity as senior process development scientist and find him one of the top 5 % employees at QSV (total staff > 135).

In my observations, I found Jignesh an intelligent, self-motivated and hardworking individual that takes great interest in engineering aspects of processes (examples are scale-up of unit operations, heat/oxygen/mass transfer and facility design). In his work, he is always proactive and takes initiatives when needed. Some recent examples where Jignesh took the lead are – the commissioning of a new high-pressure homogenizer for the process development lab, the collecting and organizing of MSDS information of all chemicals used in the process development lab and the set up of an inventory of all process development cell banks.

Jignesh is capable to apply his biochemical engineering knowledge actively and effectively. As part of his personal assignment, Jignesh worked on a facility design project. For this he worked on cost and facility layout aspects, reviewed PFDs (process flow diagrams), designed mass balance spreadsheets and performed process simulations. Jignesh is a strong, reliable contributor to our team producing high-quality work in a timely manner in all the projects he is assigned to.

His health and safety record is excellent with no major or minor incidents in the last three years. He has always complied with our internal health and safety regulations and has worked within international regulations (ICH guidelines, FDA, EMEA and Health Canada) that guide our industry. Jignesh has completed various safety training such as eyewash & fire safety training, and is also qualified on WHIMS safety.

Alberta Ingenuity Fund (AIF) is one of the outstanding engineering and research awards in Alberta for which Jignesh was nominated for two years in a row. I believe that developing quality processes and building relationships within industry is the responsibility of each QSV biologics employee, and Jignesh's consistent contributions to that end are remarkably exceptional. If you would like additional information about Jignesh, you can contact me at (780) 4385722 or per email (azeiser@qsvbiologics.com).

Sincerely,

Dr. Arno Zeiser
Sr. Process Development Scientist.
QSV Biologics Ltd.

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QSV Biologics

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www.QSVbiologics.com

February 27th, 2008

Re: Letter of Recommendation for Jignesh Padia

It is with pleasure that I submit this letter of recommendation in support of Mr. Jignesh Padia's application for IChemE Chartered Chemical Engineer status. I currently hold the position of Quality Assurance Manager with QSV Biologics, a contract biotechnology manufacturing company, and have over 20 years experience in the pharmaceutical industry.

Jignesh has been employed by QSV Biologics as a Process Development Associate since June 2005. During this period Jignesh has been actively involved in a number of process development projects. In addition to his process development activities Jignesh was also co-opted onto a multidisciplinary company task force actioned to prepare a conceptual design for an expansion facility. This role required him to ensure that the design addressed both technical processing issues and also promoted an effective and efficient process flow. The quality of his input to this task force was recognized at the highest levels within the company.

I have always found Jignesh to be an intelligent, hard working, ethical and motivated employee. He is able to grasp ideas quickly and has the mental agility to 'run' with those ideas and apply them to real world problems. Jignesh has acted as Lead on a number of PD projects that have been completed successfully and his leadership skills will likely see him take on additional responsibility within the company as his career develops.

As a pharmaceutical manufacturer QSV Biologics must conform to the Good Manufacturing Practice quality standards established by both national and international regulatory bodies (e.g. Health Canada, US FDA, ICH). These standards include all aspects of the more widely adopted ISO quality standards but also incorporate additional safeguards to protect our ultimate customers: patients. Jignesh's involvement with the expansion project mentioned above was effective because he had a sound understanding of GMP requirements. The full impact of GMP is not typically experienced by PD personnel and hence the fact that Jignesh understood these requirements so well is a testament to his intellect and ability to quickly grasp new concepts.

Jignesh has also served as a member of the company Health and Safety Committee and in this role has displayed a sound understanding of safety requirements and loss prevention strategies. Jignesh recently completed an overhaul of PD MSDS documentation to ensure that his group was in compliance with company safety standards. Jignesh's involvement with the H&S Committee was very much appreciated by Management.

I strongly support Jignesh's application for IChemE status and believe he would be an asset to your association. Please feel free to call me at (780) 237 6704 if you require additional input.

Sincerely,

Stuart du Kamp
Quality Assurance Manager

Quality and Speed build Value

Continuing Professional Development Record for Jignesh Padia

Category: Business Development and Project Management
Date: June 2005

I prepared a project proposal for Helix Biopharmaceutical's recombinant protein product and prepared the cost analysis. The project proposal involved the technical aspects of fermentation and downstream processing for recombinant protein. I took a lead role and was designated as an acting project manager during the transition period and joining of new project manager.

During this period I was responsible for collecting input from quality control & manufacturing departments of QSV for a detailed project scope. Using this input I prepared a presentation covering process changes, project cost & feasibility and Gantt chart to CEO and other management team members. I was given a task to downsize this project scope from $1M to $ 500 K and to segregate into multiple phases. I demonstrated my biochemical engineering training by providing experimental plan and by providing information on process compression to achieve the target cost and proposed a two phase project scope.

As a part of this exercise I effectively demonstrated my knowledge of downstream processing gained from my previous work experience at Millipore and helped move the relationship towards signing the letter of intent with Helix Biopharmaceuticals.

Mr. Jignesh Padia
Process Development Associate
M.Sc. Biochemical Engineer
QSV Biologics Ltd.

Dr. Graeme Macaloney
C.Eng., F.I.Chem.E.
Founder, President & Chief Executive
QSV Biologics Ltd

Quality and Speed build Value

Continuing Professional Development Record for Jignesh Padia

Category: Business Development and Project Management
Date: June 2005

I prepared a project proposal for Spinewave Inc. for their recombinant protein product. I lead our team for technical discussions with client's team and provided in depth technical analysis of the project and proposed a plan for a process development. Client's small scale process had several centrifugations and precipitation steps, which were potentially problematic to scale-up and optimize with changing process scale. New proposed process replaced these complicated unit-operations such and replaced with scalable cascade filtration unit-operations. These proposed changes can potentially bring advantages to both sides by having a process compression resulting in higher yield for Spinewave and less capital investment in equipments for QSV.

For this I prepared a project Gantt chart and did the cost analysis for the entire project based on the standard assumptions and information provided to me during the technical discussions. I also gave an oral presentation to the client and discussed the process issues. I collected information from quality control and manufacturing department managers and analyzed it to prepare a feed back for this project. Effective communication with other team members and interdepartmental members was of prime importance during this exercise.

Jignesh

Mr. Jignesh Padia
Process Development Associate
M.Sc. Biochemical Engineer
QSV Biologics Ltd.

Dr. Graeme Macaloney
C.Eng., F.I.Chem.E.
Founder, President & Chief Executive
QSV Biologics Ltd