CONSIDERATIONS FOR BEST PRACTICES IN APPLICATION OF BIG DATA IN PHARMACEUTICAL MANUFACTURING AND SUPPLY CHAIN

NUSAGE – PharmEng
Pharmaceutical and Biotechnology Training Program
Shaping Human Capital for Challenges in the Pharmaceutical Industry
Course Details.

Instructor:
Fergus Buckley, BSc (Chemistry), Msc (Business Analytics and Big Data) has more than 18 years of experience in pharmaceutical manufacturing in in quality, validation/commissioning & qualification and lean process improvement roles. He is an expert in the context of current GMP and lean process improvement, and has served major multinational pharmaceutical companies like Merck, Sharpe & Dohme, Johnson & Johnson, Amgen, Sanofi, GSK as well as medical device companies such as Boston Scientific and Stryker on four different continents (Australia, Europe, Asia, North America). He has successfully acted a QA and C&Q lead on a range multimillion–dollar, greenfield and facility upgrade, FDA Regulatory compliance remediation, retrospective validation and process characterization / lean process improvement projects with quantifiable results such as the successful attainment of 100% clean utilities process validation completion at GSK Bio, among others. Fergus has a Six Sigma Black Belt certification and he has recently completed a Master programme in Big Data and Business Analytics at IE Business School in Madrid, Spain, one of the top 10 business schools worldwide.

Date and Time:
2019 (refer to website www.pharmeng.asia for latest dates)

Course Outline
1. **Introduction to Big Data** (data formats, technologies and handling techniques) and the fourth industrial revolution.
   - Data explosion - worldwide {3 v’s of big data ;Variety, Velocity, Volume}
   - Data Science v Data Mining, Data handling, Data lake, Big Data Ecosystems
   - How to maximise the value of data.
2. **Big Data Analytics techniques as the basis for Continued Process Verification** - Introduction and demonstration;
   - Statistical Process Control using process data streaming.
   - Using data viz to identify patterns in the data (scatter plots, paretos, histograms, box plots, capability plots etc)
   - Using statistical techniques to understand the data (confidence intervals, correlations,
   - Use of Machine Learning techniques to identify the optimal parameter ranges.
3. **Pharma Manufacturing Equipment Maintenance** - Introduction and demonstration;
   - How to derive efficiencies in predictive maintenance programme through modelling techniques.
   - Understand and pinpoint machine breakdowns using Machine Learning.
   - Quantify reliability on machine and even part level.
4. **3 x Case Studies**
   - Manufacturing equipment preventative maintenance using predictive modelling techniques.
   - Manufacturing SPC using shop floor data streaming.
   - Manufacturing Data Viz exercise.
5. **Quiz and group participation**
   - Course Handouts – comprehensive templates and examples to help you with implementation.

Course Learning Outcomes
Upon completion of this course the attendees will be able to:
- Gain an understanding of a practical approach to harnessing the power of Big Data in pharma manufacturing.
- Gain an understanding of the application and benefits of Predictive Modelling in Engineering maintenance
- Learn the benefits of performing Lean Process improvement using digital analytic techniques.
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Objective
This course provides an overview of the concept, tools, infrastructure and techniques which can be grouped together under the parent term of ‘Big Data’

The objective of this course is to guide the attendees through the following concepts;

- Firstly, what is Big Data and the Fourth Industrial Revolution?
- How can large volumes of data be handled effectively in a Pharmaceutical Manufacturing Environment?
- How can big data techniques be applied effectively and successfully in a Pharmaceutical Environment?
  - Specifically, how can areas like manufacturing process quality and yield and equipment maintenance be improved, optimized through the use of big data analytics techniques
  - What are the challenges?
  - What are the benefits?

Description
Over the past 20 years, with the advent of six sigma methodologies; pharma manufacturers have been able to reduce waste and variability in their production processes, leading to increased product quality and yield. However, due to the number and complexity of production activities in pharma and specifically biopharma manufacturing (which can contain up to 200 production variables), extreme swings in the yield and quality of product are the reality, even after the application of lean process improvement techniques. Additionally, with the increased FDA focus on continuous process verification, the need for manufacturers to use a more detailed, more granular approach to diagnosing and correcting process flaws is obvious. Big Data and advanced digital analytics can provide such an approach.

This course will give the attendees a practical introduction to the world of Big Data and Digital Analytics and will present the many different technologies and techniques which can be used to optimise process characterisation and understanding to extract not only maximum product yield and quality but also business insights from large volumes of available data.

To reinforce the learnings, course attendees will be led through three practical use cases

1. **Process Understanding through Data Visualisation tools**
   Traditionally pharmaceutical process visualizations have been performed through small scale excel based tools – meaning that many more complex data relationships, correlations, interlinkages and dependencies can be missed. With the increasing availability of shop floor data and with techniques such as data streaming now commonly in place, more complex and thorough data visualization techniques can now provide more valuable insights in the data. This case study will present alternative data visualization techniques which can be used to highlight such features in process data – which can then be used to perform root cause analysis, process characterization and optimization techniques.

2. **Predictive Modelling for Process Equipment Maintenance**
   Big data technologies are presenting companies with the very real possibility that equipment maintenance schedules can be derived based on the historical analysis of past failures rather than the quarterly preventative maintenance schedules that many companies traditionally operate. This case study, will present an instance where predictive modelling based on historical data can accurately predict when and where machines will break down based on past use, facilitating a more targeted and cost effective maintenance approach.

3. **SPC using Data Streaming**
   This case study will present a practical use of streamed shop floor data and will introduce different statistical analysis techniques that can be used to derive real time insights into the performance of a manufacturing process, facilitating a more pro-active approach to process monitoring.
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Course Registration

To register for this course or for any other course enquiries, please contact:

Ms CHEW Ying Ying
Senior Manager
Office: S4A 03
Tel: 65168977
Email: phacyy@nus.edu.sg
PharmEng Technology ("PharmEng"), a division of PEPharma Inc., provides professional development and certification training programs throughout North America and Asia. We deliver over 35 courses to the pharmaceutical, biotechnology, nutraceutical and medical devices industries in the areas of:

- cGMPs
- Validation
- Engineering
- Project Management
- Medical Devices
- Quality Compliance
- Quality Assurance
- Regulatory Affairs
- Manufacturing

**Why PharmEng Professional Training?**

- Unique curriculum that covers key areas critical to the success of the industry, through courses that integrate theory and practice
- Advisory committee that includes members from industry, academia and government, ensuring that important regulatory and industry issues are addressed
- Custom courses that cover both general and basic “know-how” as well as current challenges, issues and new developments in the industry
- Instructors that have been selected among industry leaders and subject experts who will provide challenging course work and valuable hands-on experience

PharmEng delivers courses to two distinct groups:

1. **Corporate Training:** Experienced industry professionals who require current best practices in order to keep up-to-date with industry standards, Good Manufacturing Practices (GMP’s) and regulations.
2. **Career Training:** Next generation individuals seeking careers in the industry who need practical skills and “know-how” for the pharmaceutical and biotechnology workforce.

For those individuals requiring one day professional development programs, courses are available through any of the PharmEng offices located throughout North America and Asia with access to course listings, course availability and registration through the PharmEng website www.pharmeng.com.
Certification Programs

For career training and certification, PharmEng offers programs through national and internationally-recognized universities delivering certificate programs such as:

The Biopharmaceutical Technology Certificate Program for the University of Waterloo and the National Tsing Hua University College of Life Science in Taiwan

The Biotechnology and Pharmaceutical Technology Program for Cape Breton University

Instructors and Course Materials

All instructors are subject matter experts with direct industry experience. Instructors include guest speakers from industry, government and academia. Course materials are developed by PharmEng in-house and are constantly updated to keep current with the regulatory environment. As the industry changes, so do the issues and challenges.

Our courses, with supporting materials, link together:

- Training
- Regulations
- Government
- Industry
- Academia
- International Standards

Conferences

PharmEng offers conferences throughout the year in collaboration with Health Canada, and various professional associations in biotechnology, pharmaceutical, medical devices, nutraceutical and healthcare industries.

“Best instructor and best coverage of this subject that I’ve experienced yet. Great session – so glad I came.”
- IMRIS Inc.

“…good course, especially the case studies.”
- Genesys Venture Inc.

“It was a nice change that the instructor had personal experience that I could relate to.”
- Medicure Inc.
### Current Good Manufacturing Practices
- GMP – Get More Productivity
- GMP – Concepts and Implementation
- cGMP’s for Drugs and Active Pharmaceutical Ingredients Manufacturers

cGMP training is tailored to meet your company’s specific needs in one or all of the following areas:
- Engineering
- Production
- Packaging
- Quality Assurance
- Quality Control
- Regulatory Affairs
- Clinical Research
- New Drug Submission/Application
- Natural Health Products
- Active Pharmaceutical Ingredients
- Medical Devices
- Blood and Blood Products
- Practical cGMP

### Regulatory Affairs
- Good Clinical Practices (GCP)
- New Drug Application/Submission
- Chemistry, Manufacturing and Control
- Natural Health Products Registration

### Quality and Compliance
PharmEng® also provides customized Good Laboratory Practices (GLP) and Good Clinical Practices (GCP) training to clients in order to assist companies in moving forward with their pre-clinical and clinical trials.
- Master Plan – Roadmap to Compliance
- Good Laboratory Practices (GLP)
- Pharmaceutical Quality Assurance and Control
- GMP Programs – Planning and Implementation
- Audit Programs and Annual Review
- Recall and Compliant Systems
- Standard Operating Procedures
- Corrective and Preventative Actions (CAPA)
- Risk-based Approach to Inspecting Quality Systems

### Medical Devices
- Medical Device Regulatory Requirements
- Quality System Requirements – ISO 13485
- Quality Systems for Medical Devices

### Manufacturing
- Manufacturing Control in the Pharmaceutical Related Industries
- Pharmaceutical and Biotech Manufacturing Processes
- Active Pharmaceutical Manufacturing
- Solid and Semi-Solid Dosage Manufacturing
- Aseptic Manufacturing
- Sterile and Septic Processes

### Engineering
- Commissioning and Validation of Pharmaceutical and Biotechnology Facilities
- Design and Validation of Critical Utility Systems
- Process Analytical Technology (PAT)
- Design and Commissioning and Validation of Pharmaceutical and Biotechnology Facilities

### Validation
- Analytical Methods Validation
- Process Validation
- Cleaning Validation
- Computer Systems Validation
- Validation of Sterilization Processes

### Project Management
- Project Management in a Regulatory Environment
- Project Management for Clinical Research Studies