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

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 Environment?
- What are the challenges?
- How can big data techniques be applied effectively and successfully in a Pharmaceutical Environment?

Description

Data science now plays an important role in many industries and is just starting to make a meaningful impact in the Pharmaceutical Industry, particularly in the R&D / Clinical Trial, Manufacturing and Supply Chain sectors of the industry. The benefits of being able to mine large volumes of data to gain valuable insights are multi-fold; however to be able to get to this position, companies are required to change infrastructure, culture and working practices to be able to mine this information effectively. This course will give the attendees a practical introduction to the world of Big Data and will present the many different technologies and techniques which can be used to extract maximum value and business insights from large volumes of data. Additionally, Course attendees will be led through three practical use Big Data use cases:

1. **Big Data application in Pharmaceutical Clinical Trials Management**

   Traditionally clinical trials have used only structured, clinically-sourced data and stored in spreadsheets (e.g. excel). This data which was relatively easy to organize and mine due to its relatively small size – But, with the advent of Big data, more and more companies are now using cloud based storage for their data which is facilitating much larger study populations and datasets. The challenges for pharmaceutical companies is to implement the correct infrastructure and expertise to be able to mine these massive datasets to derive value from their studies; to analyze very large amounts of data quickly.

2. **Big data applications in Pharmaceuticals Manufacturing**

   The opportunities for big data applications in manufacturing are numerous, from live streaming and processing of manufacturing data to predictive modelling – this course will focus on the application of machine learning techniques to implement a predictive modelling approach to machine maintenance. The advent of these technologies are presenting companies with the very real possibility that they can move on from the traditional approach to preventative maintenance (i.e. quarterly pm schedules for example) to pm schedules that are derived from predictive modelling based on historical data – modelling that can accurately predict when and where machines will break down based on past use, facilitating a more targeted and cost effective maintenance approach.

3. **Big data applications in Pharmaceutical Supply Chain**

   Recent changes in serialisation regulations including, The FDA Drug Supply Chain Act and the EU Falsified Medicines Directive are requiring pharmaceutical manufacturers, packagers and distributors to collect more and more data – the challenge for companies is to look beyond the significant implementation costs to meet these regulations and look at ways to derive a significant ROI by being able to process, identify, understand and ultimately derive business insights from this valuable data.
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Course Details

Instructor:

**Fergus Buckley, BSc (Chemisty), Msc (Business Analytics and Big Data)** has more than 20 years of experience in quality and validation/commissioning and qualification. He has worked with a range of multi-national pharmaceutical and medical device companies such as, Merck Sharpe & Dohme, Ethicon/J&J, Amgen, Sanofi, Boston Scientific and Stryker Instruments in four different continents (Australia, Europe, Asia, N. America).

He has successfully acted a QA and C&Q lead on a range multimillion-dollar, Greenfield and facility upgrade projects. He is an expert on GMP & Compliance in addition to C&Q Regulations. Recently, he completed a Msc in Big Data and Business Analytics at IE Business School in Madrid, Spain, at a top 10 Worldwide ranked business school.

Date and Time:

2018 (refer to website [www.pharmeng.asia](http://www.pharmeng.asia) for latest dates)

Course Outline

- Introduction to Big Data – data formats, technologies and handling techniques
- Linear v Exponential Data
- 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
- Machine Learning and Unsupervised v Supervised Learning techniques
- Case Studies – Presentation of three uses cases in areas of Clinical Research, Manufacturing, Supply Chain
- Quiz and group participation
- Course Handouts – comprehensive templates and examples to help you with implementation.

Learning Outcome

Upon completion of this course the attendees will be able to:

1. Gain an understanding of the applications of big data in Supply Chain, Clinical Trials and Manufacturing environments
2. Gain a basic understanding of the concept of machine learning and the benefits that can be derived from predictive modelling
3. Understand the different types of data, Transactional, Structured, Unstructured and how to best handle, store, extract and transform these types of data
Course Registration

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

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PHARMENG TECHNOLOGY

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.

“It was a nice change that the instructor had personal experience that I could relate to.”
- Medicure Inc.

“...good course, especially the case studies.”
- Genesys Venture Inc.
ABOUT THE TRAINING PROVIDER

PHARMENG CORE TRAINING COURSES

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

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

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

PharmEng Technology, a division of PE Pharma Inc., headquartered in Toronto, Canada, is a full-service consulting company that serves the pharmaceutical and biotechnology industries internationally. Consulting services include project management, engineering, cGMP, validation, calibration, regulatory compliance and certified training.