ODIN Spring Courses 2018

Quality by Design - QbD

Wednesday, January 24th, 2018.

Background: The course gives an introduction to the Quality by Design philosophy. QbD has caused a big paradigm shift in the pharmaceutical industry from simple experimental methodologies to more science and engineering based approaches involving risk assessment, design of experiments, modelling and introducing more advanced monitoring and control tools.

The regulatory authorities encourage the industry to embrace QbD as it has shown to create better product understanding which ultimately improves quality to the benefits of the patients. Companies that apply QbD during development, achieve improved process and product understanding and better economics. The course participants will get a basic understanding of QbD thinking and the main tools e.g. risk assessment, design of experiments, modelling and process analytical technology (PAT) through small exercises and case stories from the pharmaceutical industry.

Though examples are from the biopharmaceutical industry the QbD tools have general applicability in many industries.

Audience: Scientist and engineers involved in product and process development which would like to get an overview of QbD tools and to get inspiration for further professional development. Managers leading development teams looking for inspiration on how to develop formulations and processes.

Teacher: Erik Skibsted, Principal Scientist PhD, Novo Nordisk
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Erik Skibsted has a master degree in chemistry from the Technical University of Denmark and a PhD degree from the University of Amsterdam in the field of near-infrared spectroscopy, chemometrics and solid dosage form manufacturing. He has worked at Novo Nordisk for 18 years in various areas like protein characterization, process trouble shooting, process analytical technology and Quality by Design.

The course is taking place from 10 AM to 4 PM. Lunch and coffee will be included. If you have special dietary needs, please let us know by enrollment. Lectures and notes are in English.

Enrollment ended December 1st, 2017.

Near-infrared (NIR) Spectroscopy

Thursday March 22nd, 2018

Background: This course aims to make the participants familiar with the basic concepts and physics of non-destructive NIR sensors utilized for in-, on- and at-line process monitoring and quality control in the modern food and medicinal industry. The course is designed to give the participants an introduction to the basic theoretical background, hands-on experience with NIR spectroscopy and the subsequent multivariate data analysis of NIR data.

The course will provide the participants with the necessary background knowledge to:

- understand NIR spectroscopic methods (vibrational spectroscopy)
- understand advantages and disadvantages of NIR measurements
- operate spectroscopic NIR equipment
- choose NIR equipment and sampling
- read NIR spectroscopic expert and research literature
- use multivariate data analysis for handling NIR data

Audience: The course is of importance to engineers and technologists working e.g. in the food and medicinal industry engaged in on-line process monitoring. The course will provide an overview of the requirements and resources needed in order to implement NIR.

Teachers: Søren Balling Engelsen and Frans van den Berg

Location: University of Copenhagen, Frederiksberg Campus. The course is taking place from 10 AM to 4 PM. Lunch and coffee will be included. If you have special dietary needs, please let us know by enrollment. Lectures and notes are in English.

This ODIN course is limited to three persons per membership. Enroll to Rasmus Bro (rb@food.ku.dk) March 10th 2018 at the latest. Enrollment will be accepted only through your ODIN representative. Please provide e-mail address of course participants so last minute details can be provided. Cancellations must be made no later than three days in advance or a fee of 500 DKK will be charged.

Basic Chemometrics

Thursday to Friday, April 5th to April 6th, 2018.

Background: Chemometrics (or multivariate data analysis) may be used to solve problems involving large amounts of data. This is relevant within fields such as development, research, process monitoring and control, and laboratory analysis. In these fields, the use of single variables is often inadequate to describe, differentiate or classify objects/samples. Looking at more variables at a time ensures that interactions, patterns and correlations are taken into consideration. Combined with superior data visualization, chemometrics is a needed tool for proper data analysis.

As participant you will be introduced to the multivariate way of thinking and learn how to explore your data properly and how to set up a multivariate calibration/regression model. The course is a mixture of lectures and exercises. In the exercises, you will use the chemometrics tools. You will learn to navigate through the raw data, develop models and visualize the models. During this course you will *not* be able to work with your own data.

Audience: The course is intended for people handling problems where chemometrics may be applied or people who have a general interest in learning more about chemometrics and its applications. Some mathematical and statistical expressions will be used in the course and a variety of data (e.g. sensory and spectroscopic data) will be used as examples.

Software: PLS_Toolbox will be used during exercises and has to be installed on your own laptop.

Teachers: Marta Bevilacqua and Rasmus Bro

Location: University of Copenhagen, Frederiksberg Campus

The course is taking place from 9 AM to 5 PM both days. Lunch and coffee will be included. If you have special dietary needs, please let us know by enrollment. Lectures and notes are in English.

This course is *not* limited to three persons per membership. For this occasion only, we allow more participants. We will aim at no more than 30 students in total. Enroll to Rasmus Bro (rb@food.ku.dk) March 21st, 2017 at the latest. Please provide e-mail address of course participants so last minute details may be provided. Cancellations must be made no later than four days in advance or a fee of 500 DKK will be charged.

Design of Experiments

data • information • control

Tuesday to Wednesday, May 8th to May 9th, 2018.

Background: Proper analysis of data and efficient planning of experiment is (or should be!) a part of every scientist's toolbox. In this short course, an outline of different terms within Design of experiments and the theory behind when to use what are given. After a reminder on the basics of statistics and populations required for experimental planning (sampling, univariate linear regression, etc.) we will look at the setup and analysis of designed experiments and statistical inference from designed data (Designs, ANOVA, etc.). Furthermore, we will discuss efficient planning and performance of fixed pattern and sequential optimizations techniques useful in e.g. yield optimization in production processes or instrumental optimization in analytical chemistry procedures.

Audience: The course is intended for people handling problems where using Design of experiments can be an advantage when setting up the experiments or people who have general interest in knowing how to setup and use experimental designs. Simple mathematical and statistical terms will be used in the course and the theory will be accompanied by computer exercises.

Software: JMP (SAS) or MODDE (Umetrics) can be used during exercises.

Teacher: Frans van den Berg.

Location: University of Copenhagen, Frederiksberg Campus.

The course is taking place from 9 AM to 4 PM both days. Lunch and coffee will be included. If you have special dietary needs, please let us know by enrollment. Lectures and notes are in English.

Please note that a minimum of 8 participants must sign up for this course to take place.

This course is *not* limited to three persons per membership. For this occasion, we allow more participants. We will aim at no more than 30 students in total. Enroll to Rasmus Bro (rb@food.ku.dk) May 1st, 2018 at the latest. Enrollment will be accepted only through your ODIN representative. Please provide e-mail address of course participants so last minute details can be provided. Cancellations must be made no later than three working days in advance or a fee of 500 DKK will be charged.

Multivariate Statistical Process Control (MSPC)

data • information • control

Wednesday May 16th, 2018

Background: Processes in the food and biotech industry have become more complex, and the number of *on-line* measurements / process-tags with no direct relation to e.g. product quality (e.g. temperature, speeds, residence times, operation stages) is growing steadily as well. Statistical Process Monitoring and Control is a branch of applied statistics that looks at modelling and following changes in dynamic processes, for both continues and batch operations. It differs from traditional *engineering control* in that soft statistical modelling tools – rather than *hard* mathematical models - are used to describe and follow the performances of the process. We will start with a brief reminder on the most common univariate statistical process control charts, the connection to engineering control and their application areas.

The main subject of the day is Multivariate Statistical Process Control, methods inspired by chemometric modeling methods like PCA and PLS. These advanced statistical approaches identify the critical variables and underlying patterns in a data set. They also show the relationships between variables and how they impact one another, trying to understand complex process behavior. Next to the (basic) theory – which is not different from chemometric modelling - we will study literature and practice examples of MSPC, the organization and *clean-up* / pre-processing of process data, and some future developments in statistical process monitoring.

Audience: The course is of importance to engineers and technologists working e.g. in the food and pharma and biotech industry engaged in statistical process analysis (using e.g. historic data) and/or on-line / real-time process monitoring. The course will provide an overview of all the requirements and resources needed in order to make use of multivariate SPC, but a prior basic knowledge / understanding of chemometric modelling is beneficial.

Teachers: Frans van den Berg

Location: University of Copenhagen, Frederiksberg Campus

The course is taking place from 9 AM to 4 PM. Lunch and coffee will be included. If you have special dietary needs, please let us know by enrollment. Lectures and notes are in English.

This ODIN course is limited to three persons per membership. Enroll to Rasmus Bro (rb@food.ku.dk) May 1st 2018 at the latest. Enrollment will be accepted only through your ODIN representative. Please provide e-mail address of course participants so last minute details can be provided. Cancellations must be made no later than three days in advance or a fee of 500 DKK will be charged.