

## Minutes QbD WP meeting 1

15 April 2015, 13:00- 16:00, Dechema, Frankfurt (Germany)

### Participants:

Jarka Glassey (Newcastle University)  
Max Barolo (University of Padova)  
Christoph Herwig (Technical University of Vienna)  
Zoran Novak (University of Maribor)  
Krist Gernaey (Technical University of Denmark)

### Via Skype:

Thomas De Beer (Ghent University); 13:15 – 14:30 h  
Norbert Kockman (Technical University of Dortmund); 14:30 – 15:30 h

#### 1) Welcome (KVG)

#### 2) Approval of the agenda

Agenda was approved

#### 3) Short introduction of the participants (All)

All meeting participants made a brief introduction about themselves and their research group. Below the summary, with a few keywords describing the main competences / interests of the meeting participants.

- Jarka Glassey – data driven modelling, multivariate analysis, rapid bioprocess development
- Max Barolo – Process Systems Engineering (PSE), multivariate analysis
- Krist V. Gernaey – PSE, mathematical modelling, scaling up/scaling down, continuous production, fermentation technology
- Christoph Herwig – Production of recombinant proteins/biopharmaceuticals, scaling up/scaling down, rapid bioprocess development, measurements/data quality
- Zoran Novak – High pressure technology and supercritical fluids, enzymes (immobilization), separation processes
- Thomas De Beer – Measurements, continuous manufacturing, freeze drying
- Norbert Kockman – Equipment design, small-scale equipment for small-scale chemical production.

#### 4) What should the QbD Working Party focus on?

- Integrating the working party (WP) activities with other WPs, since the QbD activities will bridge across different WPs. We can (and should) also interface to the regulatory agencies. **Our task should be to propose workflows linking the different elements together that are normally considered important in a QbD context.**
- The QbD WP spans very broad (from primary manufacturing to secondary manufacturing). Thomas de Beer: many guidelines explain what should be done, but not how to do it. We can focus on this, for example by preparing case study examples.

- It could be considered to build a bridge to the IFPAC organization. They have a yearly meeting in the US, and a bi-yearly meeting in Europe.
- Proper definitions are needed in order to avoid any future confusion about QbD. Quality should be introduced in the Quality by Design thinking. Definition of terminology! How should we do this?
  - Make a couple of slides (also present at ESCAPE)
  - Make a short description for the website (EFCE and Dechema website)
  - Flyer to distribute
  - Request to be part of the EFCE newsletter following this meeting
  - Involve companies (what are their needs?) – Send out a questionnaire? Organize expert panel meetings and end up with a position paper after each meeting.
- In order to present ourselves as a WP, we should prepare a list of challenges as a starting point. All members should be asked to give input about the main challenges in our area.
- Prepare some courses at PhD level (on the long run)
- Is QbD interesting for the companies? Why? Economic advantages? Or because they are forced to it. Can the companies give examples of QbD related projects. What have the drivers and objectives been of the projects they had related to QbD. [Thomas de Beer: economic driver; and regulatory (companies are now encouraged to do it, but they will probably be obliged to do it later on).
- We need integrated approaches that can be applied to different problems. Scalability of design space is for example a big issue. Transfer of knowledge (models, procedures) across different equipments.
- Can we attract funding to support the WP activities? For example from EU? Travels for the WP meetings could be funded via COST action? Rise – exchange of researchers (meeting)? Danish foundations?

#### 5) WP membership – future strategy

- We need to have a clear strategy / future plans to extend the number of members of the WP. **We need to pay special attention to attracting good candidates from industry**
- Only 2 members per country allowed, in principle. But this puts a major constraint on what we can do! We can have as many members as we wish, but they will be guest members (with an interest in the activities of the working party). We are not limited to the number of guest members.
- Representation of a range of companies (large and SME, producers and suppliers) in the WP would be ideal
- Regulatory members, associated members? We could invite them as guests to join some of the meetings? People working in Q/A departments in the companies could also be relevant to invite.

#### 6) WP initiatives/activities – planning

- Make a one page flyer – what is our mission? Differentiation. Where are we and where are the others!

- **Start with a position paper.** What is the target audience? Industry! But we need some industrial people to join such an effort as well. Describe what the WP will focus on. Definition of terms. Define the limitations of the regulatory documents and the challenges for industry/academia to interpret these documents.
  - Where do we publish such a position paper? Pharmaceutical technology, pharmaceutical engineering, PDA journal, Chemie Ingenieur Technik, Journal of Pharmaceutical Innovation.
  - Define one or two benchmark problems suggested by industry? With some data people can work on.
  - Courses? Conference participation with special session? Workshop organization at conferences? Other 'network-wide' activities?
  - Research money – could also be applied for with the WP members. Three topics to focus on – scalability, continuous production, knowledge transfer
- 7) WP newsletter
- Distribution list?
- 8) Future WP meetings – planning
- Nice, ECCE conference, **Monday 28** September (Tuesday 29 for ESBES M3C meeting) Lunch break if there is more than 1 hour time. Otherwise after the sessions
  - Prepare 3 or 4 slides to make publicity for the QbD WP.
  - Telcon meeting – put aims/objectives together (challenges / structure of white paper) and then have a telcon meeting
  - February-March 2016 – at Dechema
  - September 2016 – Dublin – ESBES conference – organize a special session (who to run it, how to run it; presentations + discussion afterwards? Industrial panel?)
  - 2017 – Europact (In France, probably Montpellier, February March 2017, probably)
  - World Congress of Chemical Engineering (October 2017, Barcelona)
- 9) Any other business
- None

### To do

- Ask for challenges (all)
- Identify industry members that can join the preparation of a position paper
- Organize a telcon meeting by the end of May (make a Doodle)
- Work on position paper ideas via Google Docs

- Contact journals (editors) related to position papers