

## Minutes QbD WP meeting 2

28th September 2015, 13:00- 15:00,

10th European Congress of Chemical Engineering Nice, (France)

### Participants:

Jarka Glassey (Newcastle University)  
Norbert Kockmann (Technical University of Dortmund)  
Christoph Herwig (Vienna University of Technology)  
Krist Gernaey (Technical University of Denmark)

### Via Skype:

Max Barolo (University of Padova)

#### 1) Welcome (KVG)

#### 2) Approval of the agenda

- Agenda was approved

#### 3) Interactions with M3C

- M3C decided to apply for a COST action in order to acquire funding that could boost the organization of M3C related meetings (COST actions mainly cover travel costs, as well as short exchanges of students). It was decided to join this application. The next deadline is January 2016 [Update: this deadline has been moved to April 2016]. It was decided to prepare this COST application (CHE). Prerequisite is the positioning via a slide set as defined in Meeting 1 (KVG). CHE suggested to involve also Anurag Rathore in this application as an external expert.

#### 4) Positioning and Transparency of Activities of the Working group

- Prepare slide set as agreed in Meeting1 (KVG), targeted 30th September 2015 to CHE
- Flyer to be defined after Slide Set
- Course Gent 2015, Jarka gets this published via Dechema/Ines Honndorf
- Workshop on Accelerating Bioprocess Development held by CHE in Vienna in June 2015
- Francesca Marrani, Max Barolo organize a local workshop in Italy on QbD in 2016! Focus on industrial needs
- Set up a session at ESBES! Same time as PROCESSNET meeting and IMRET (KVG to contact JGL)
- Do something similar at a conference with focus on chemical manufacturing - ChemSpec? Chisa (28-31 August 2016; Jarka will check)?
- CHE informed that ISPE will now establish a working group on biotechnology, 4 working groups have been founded (e.g. Process science, quality and regulatory, Innovation and knowledge management)

## 5) Position paper

- Involve industry and involve regulatory bodies in preparation?
- Brainstorm on the scope of the position paper:
  - Focus on need for workflows / bridging academic tools with industrial needs
  - Focus on areas where more work is needed to push acceptance of QbD
  - Enable industry to carry out QbD
  - Define a number of case studies?
  - Computational model life cycle management - tracing the model
  - Knowledge transfer / transfer of model between different equipments / processes
- Use that as WPs for the COST proposal
- Timeline: TOC (KVG) to be prepared by 15 October, 15 November input text
- Which journal?- OPRD; International Journal of Pharmaceutics? Journal of Pharmaceutical Innovation; PDA Journal (Anurag Rathore is one of the associate editors).
- Contact journals (editors) related to position papers

## 6) WP membership - future strategy

- Delegate acquisition from industry
- Large companies as targets for higher impact
- Brainstorm list:
  - Pfizer, Boehringer Ingelheim (CHE, Bayer Pharma, GSK (MBA, JGL), Sanofi (JGL), Fujifilm (JGL), Janssen Pharmaceuticals, Novo Nordisk (KVG), Merck, Lundbeck?
  - Service providers (hesitant to take them in): Novo Nordisk Engineering (NNE-Pharmaplan), GEA, Sartorius
- Prerequisite for approaching is positioning via slide set.

## 7) Next meeting

- February 18, at Dechema, Frankfurt, Germany

## 8) Any other business

- None

Responsible for the Protocol:  
CHE, KVG, 20.2.2016