Science based design of formulations and manufacturing processes for oral solid dosage forms – from preformulation to capable commercial processes

APV Expert Workshop: Manufacturing Classification System (MCS) Expert meeting

09 to 10 May 2017
Berlin, Germany

Course No. 6693

Hot Topics

MAKING SCIENCE WORK

Objectives

An international cross-industry and academia working group has proposed the development of a Manufacturing Classification System (MCS) for oral solid dosage forms based on processing route.

The question of which route of manufacturing best to select for the commercial manufacturing of a new solid drug product appears to be an important decision for both new chemical entities and new generics and should be based on scientific data and the specific properties of both, the compounds and dosage forms. However, due to multiple challenges this has not always been the key driver in decision making at most companies in the past, as quite obvious when reviewing products currently on the market or in development.
In order to help the formulator and process scientists to come up with a scientific rational for their decision which could be applied throughout the industry and justified both, internally and in a marketing authorization, a first preliminary concept has been published in 2015 by the group as "A proposal for a drug product Manuafacturing Classification System (MCS) for oral solid dosage forms" (M. Leane, K. Pitt, G. Reynolds; Pharm Dev Technol, 2015; 20(1); 12-21) and has been further updated by the inputs from several international conferences since then. However, the approach still lacks input from major stakeholders and needs to be progressed into a suitable working tool which can be applied widely throughout the community based on decision criteria derived from commonly accessible data.

Therefore, the MCS working group has teamed up with the APV's focus group on solid dosage forms to organize a joint expert workshop, inviting all scientist and experts across all areas of the pharmaceutical industry (from drug substance to drug product, from engineering to clinic), and experts from the regulatory authorities, as well as from manufacturers of excipients and equipment, and from all relevant areas of academia to come together and drive this initiative of a scientifically driven approach for the selection of the best route of manufacturing further forward into a widely applicable system achieving a comparable status as the BCS, but in the selection of the most suitable manufacturing approach for each compound and dosage form.

By discussing the different aspects which need to be considered and the challenges to overcome in different areas including new manufacturing technologies and continuous manufacturing this expert workshop aims to further evaluate and develop the currently available preliminary concept. Publication of the results of the workshop is planned to provide an extended guidance or decision tree approach to the scientist, the company and the reviewer when deciding on the most suitable manufacturing approach.

The workshop is designed as a networking and hands on "discussion workshop" with short introductions to the different aspects and round table discussions on different aspects.
Depending on the number of registrations and participants' personal backgrounds parallel round table discussions and specific topics will be offered.
Participants are invited to send their specific interests and questions, together with their own personal background together with questions they would like to see addressed during the workshop to the APV or to Iris.ziegler@cordenpharma.com when registering for the workshop.

Program

Tuesday, 09 May 2017 17:00 to 21:30

Welcome address
Michael Leane, BMS, UK
Iris Ziegler, CordenPharma International, Germany

Pre-dinner lecture: MCS - the story so far: Data analysis from regulatory filings and internal company data
Michael Leane, BMS, UK

Networking Dinner

Post-dinner lecture: How have we selected our manufacturing processes in the past and which price have we paid for it?… a not entirely serious review of past cases of success(?) and failure (!)
Iris Ziegler, CordenPharma International, Germany

Wednesday, 10 May 2017 08:30 to 16:45

Introduction to the workshop and questions / survey results raised by participants prior to workshop
Michael Leane, BMS, UK
Iris Ziegler, CordenPharma International, Germany

Background and rationale for decisions on manufacturing technologies today? Strategies and decision trees applied by different companies
- Corden Pharma Plankstadt - Iris Ziegler, CordenPharma International, Germany
- GSK – Kendal Pitt, GSK, UK
- Astra Zeneca – Gavin Reynolds, AZ, UK

Manufacturing Classification System (MCS) Expert meeting

- Pfizer – Neil Dawson, Pfizer, UK
- BMS – Michael Leane, BMS, UK
- Gen-Plus – Markus Dachtler, Gen-Plus, Germany
- Bayer – Speaker requested
- Catalent – Speaker requested
- Janssen – Speaker requested
- Merck KGaA – Speaker requested
- Roche – Aniko Szepes, F.Hoffmann-La Roche AG, Switzerland
- Sandoz – Speaker requested

Coffee break

Round table discussions 1

Round table discussions 2

Lunch break

Round table discussions 3

Round table discussions 4

Coffee break

Summary presentation of the results from all round table discussions and plenary discussion

End of workshop and group picture with all participants and moderators

Program is subject to change

A survey will be gathered from participants by a questionnaire which will be distributed to all participants after registration (questions are focusing on workshop topics already) and results from this survey will be fed into the round table discussions by the moderators!

Topics for Roundtables

1.) What do different functional areas define as "good API properties" for them?
- Different viewpoints from stakeholders in development and in production, between pharmacists, chemists and clinicians
- How do development stage and risk philosophy impact choices for manufacturing for NCEs and Generics differently?

2.) QbD and MCS - science based product and process understanding combined with a risk based approach for efficacious, safe and profitable drug products? How can understanding our materials better improve outcomes during development and manufacturing?
- PAT, Modelling, ICH Q12
- Can MCS and QbD be aligned or are we going to far with it all?

3.) How can Materials Science characterisation results of APIs improve outcomes for formulators and assist MCS
- Micronisation, particle shape engineering or solid amorphous systems? How much control do we really have on the properties of our APIs and when and how to apply material sciences during development?
- Investigation of impact of API attributes on CQAs of drug product and predictability of results for commercial scale

4.) What are API properties a MCS should adress to improve manufacturability?
- How to predict and adress sticking, segregation, flowability and wetting of APIs and blends
- How can manufacturing processes and excipients modify or mitigate these API characteristics in formulations applying the MCS?

5.) Can we define additional boundaries within the MCS?
- How to include biopharmaceutics, potency of APIs and stability in an amended MCS?
- How can specific dosage forms like orodispersible tablets, sustained release, pediatric dosage forms be included into the MCS?

6.) Excipients, intermediates and composite materials – how can they help?
- Improvement of API properties – how can ist work?
- Boundaries and limitations of "classical" excipients versus coprocessed excipients and API/excipient composites?

7.) MCS and Continuous Manufacturing
- Can, should or must the MCS be applied to continuous manufacturing processes?
- How do the properties of APIs and excipients impact continuius processes different or to a different extent than traditional manufacturing method

Registration by fax +49 6131 9769-69

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Location

Holiday Inn Berlin City-East
Landsberger Allee 203
13055 Berlin
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Phone: +49 30 97808-0
Fax: +49 30 298988-399
email: info@hibce.de

I herewith repealable authorise APV to use my E-mail address to send me APV relevant material including current program information. My acceptance can be cancelled at any time in writing.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
e-mail: apv@apv-mainz.de

You will receive a confirmation of your registration with the invoice.

Date

MCS Expert Meeting
Course no. 6693
from 09 May 2017 17:00
to 10 May 2017 16:45

Preformulation Toolbox
Course no. 6692
from 08 May 2017 10:00
to 09 May 2017 16:45

Registration fee

Course no. 6693
Industry 990 EUR
Authorities/Academia 495 EUR
Students* 178 EUR
(free of VAT according to § 4,22 UStG)
Coffee breaks, lunch, dinner and electronic proceedings included.

Course no. 6693 and 6692
Industry 2280 EUR
Authorities/Academia 1140 EUR
Students* 306 EUR
(free of VAT according to § 4,22 UStG)

*Limited places for full time students available; written evidence must be submitted.

Hotel reservation

Holiday Inn Berlin City-East
Landsberger Allee 203
13055 Berlin
Germany
Phone: +49 30 97808-0
Fax: +49 30 298988-399
email: info@hibce.de

Participants should make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate: 27 March 2017.

Special rate:
Single room incl. breakfast buffet from 85 EUR per night.

Mainz, February 2017

Registration
As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

Registration confirmation
After your registration was successfully processed, you will receive a confirmation.

Before the event
A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

After the event
You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

Follow-up
After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

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