

# Compliance to Air-Ventilation systems, Thermostability, CTDs and Bioprocess optimization of vaccines for global markets

## DRAFT AGENDA Shanghai 19 to 22 March 2018

| <b>DAY1, Monday 19 March- Welcome and Introduction<br/>Plenary session for all participants</b> |   |          |
|---|---|----------|
| Time  | Topic   | Speaker  |
| 9h00 - 9h30   | registrations   | SIBP     |
| 9h30 – 10h00  | Welcome Coffee  |          |
| 10h00 – 10h30   | Introduction by host, Shanghai Institute for Biological Products, Sinopharm   | SIBP     |
| 10h30 – 11h30   | DCVMN Updates: compliance, training, regulatory activities and E-learning platform  | DCVMN    |
| 11h30 – 12h30   | Bioprocess of vaccines  | AW       |
| 12h30 – 13h30   | Lunch   |          |
| <b>HVAC management Plenary session for all participants<br/>Hosted by Munters at Novotel</b>    |   |          |
| 13h30 – 14h00   | Heat Ventilation Air Conditioning (HVAC):<br>Background and introduction  | M. Ginty |
| 14h00 – 15h30   | Overview of air flow principles in<br>manufacturing and storage of vaccines   | M. Ginty |
| 15h30 -16h00  | Coffee Break  |          |
| 16h00 – 17h30   | Current and evolving standards, regulations<br>and oversight mechanisms and tools to<br>monitor air humidity and purity – global,<br>regional and WHO standards | M. Ginty |
| 17h30   | Adjourn   |          |

**DAY2, Tuesday 20 March –Thermostability of vaccines  
Plenary for all participants - Hosted by Temptime at Novotel**

| Time          | Topic   | Speaker                                     |
|---------------|---|---|
| 8h30 – 9h30   | <ul style="list-style-type: none"> <li>• Thermostability of vaccines</li> <li>• Vaccine stability study design</li> </ul>   | Ted Prusik;<br>Steve Feldman                |
| 9h30-10h30    | <ul style="list-style-type: none"> <li>• Importance of the maintaining the cold chain</li> <li>• Temperature monitoring tools</li> </ul>                                | Ted Prusik;<br>Steve Feldman                |
| 10h30-11h00   | Coffee Break  |   |
| 11h00-12h30   | <ul style="list-style-type: none"> <li>• What is a vaccine vial monitor (VVM) and how does it work?</li> <li>• How is the VVM category chosen for a vaccine?</li> </ul> | Ted Prusik; Steve Feldman<br>Temptime       |
| 12h30 – 13h30 | Lunch   |   |
| 13h30 – 15h00 | Implementation of VVM at vaccine manufacturer   | Ted Prusik;<br>Steve Feldman;<br>Xizhe Wang |
| 15h00 – 15h30 | Coffee Break  |   |
| 15h30 – 16h15 | Group activity – VVM category choice  | Participants                                |
| 16h15 – 17h00 | Group activity – VVM receipt and 37°C testing at manufacturer   | All   |
| 17h00 – 17h30 | Q&A, conclusions and follow-up  | All   |
| 17h30         | Adjourn   |   |

DCVMN Training workshop  
Shanghai, 21 and 22 March 2018

**Session A: Hands-on Bioprocess training hosted by  
GE Healthcare's Fast Trak Services Team  
Limited to 10 participants only**

**Objectives**

This course covers in-depth training on:

- 1) Upstream process development using single-use equipment at 50L scale, and hands-on bioreactor cultivation using microcarriers.
- 2) Downstream process development using chromatography purification techniques and hands-on column packing techniques
- 3) QbD best practices in process development
- 4) Process economy considerations for vaccines

**Participants Profile**

Who should attend: Research and development scientists, upstream and downstream process engineers, and manufacturing technicians in the vaccine industry.

**Expected outcomes**

At the end of the workshop participants will be able to:

- 1) Apply best practices to your vaccine process development work
- 2) Cultivate microcarrier cell culture in a single-use bioreactor
- 3) Design best in class QbD strategies
- 4) Develop vaccine chromatographic techniques

**DAY 3, Wednesday 21<sup>st</sup> March – Bioprocess session  
Hosted by GEHC at Fast Track Center**

| <b>Schedule</b> | <b>Topic</b>  | <b>Speaker</b>                                |
|-----------------|---|---|
| 9h00 - 9h30     | Welcome and Introduction to Fast Trak   | Jessy Yang, Fast Trak China Leader            |
| 9h30 - 10h30    | Introduction to process development in Vaccine production   | Mats Lundgren, Customer Applications Director |
| 10h30-10h45     | Coffee break  |   |
| 10h45- 11h45    | Vaccine upstream processing- an overview  | Jianjun Yang, Team Leader - Upstream          |
| 11h45 - 12h00   | Q&A and Discussion  | All   |
| 12h00 - 13h00   | Lunch   |   |
| 14h00- 16h00    | Hands-on: Inoculation of microcarrier culture, Bead to bead transfer in spinner flask, monitoring cells growth in microcarrier cultures | Jianjun Yang, Team Leader - Upstream          |
| 16h00 - 16h30   | Hand-on training: 50L single-use bioreactor (Xcellerex™ XDR 50)   |   |
| 16h30 - 17h00   | Discussion & Conclusion - Close of Day<br>1General  | All   |

**DAY 4, Thursday 22<sup>nd</sup> March – Bioprocess session  
Hosted by GEHC at Fast Track Center**

| <b>Schedule</b> | <b>Topic</b>   | <b>Speaker</b>                                |
|-----------------|--|---|
| 9h00 - 9h15     | Re-cap of previous day   |   |
| 9h30 – 10h30    | Vaccine downstream processing an overview                              | Mats Lundgren, Customer Applications Director |
| 10h30 – 10h45   | Break  |   |
| 10h45 – 12h00   | Hands-on training: column packing using relevant columns (AKTA™ avant) | Fast Trak Team Leader- Downstream             |
| 12h00 – 13h00   | Lunch  |   |
| 13h00 – 14h00   | QbD best practices in process development                              | Mats Lundgren, Customer Applications Director |
| 14h00 – 15h00   | Process economy for vaccines   | Mats Lundgren                                 |
| 15h00 – 16h00   | Conclusions & Closure  |   |

NOTE: A basic understanding of cell culture and corresponding techniques is required for this course.

## **Session B: Common Technical Document (CTD) held at Novotel, hosted by DCVMN & BMGF**

### **Objectives**

The workshop is aimed at

- 1) Offering background information on the CTD history, structure and adoption process by different countries and regions
- 2) Providing details of differences in requirements among countries across the globe
- 3) Considering options for a certain level of alignment of requirements
- 4) Exercising on how to prepare a CTD type of dossier

### **Participants Profile**

Participants are staff from regulatory affairs or Quality Assurance Departments from vaccine manufacturing companies having a good level of spoken and written English.

### **Expected outcomes**

At the end of the workshop participants will have

- 6) Understanding of the CTD and the different versions and requirements across the world
- 7) Understanding of the DCVMN members to work on an alignment proposal and its nature
- 8) Practice on the contents expected to be included under each section of the ICH CTD

| <b>DAY3, Wednesday 21<sup>st</sup> March – CTD session<br/>Hosted by DCVMN at Novotel</b> |   |                                |
|---|---|--------------------------------|
| <b>Schedule</b>   | <b>Topic</b>  | <b>Speaker</b>                 |
| <b>Part 1</b>   | <b>ICH and Common Technical Document</b>  |                                |
| 8h30 - 10h30  | History of ICH: The Common Technical Document, Structure and Contents               | N. Dellepiane                  |
| 9h30 - 10h30  | Q & A   | All                            |
| 10h30-10h45   | Coffee break  |                                |
| <b>Part 2</b>   | <b>Comparison of different CTDs</b>   |                                |
| 10h45- 11h30  | Contents and Structure of different CTDs  | N. Dellepiane                  |
| 11h30 - 12h30   | Results of comparative study on similarities and differences between different CTDs | N. Dellepiane                  |
| 12h30 – 13h00   | Q&A and Discussion  | All                            |
| 13h00 - 14h00   | Lunch   |                                |
| <b>Part 2 (continued)</b>   | <b>Comparison of different CTDs</b>   |                                |
| 14h00- 15h00  | Module 1<br>Countries' application forms<br>Modules 2 to 5 relevance of differences | N. Dellepiane                  |
| 15h00 – 15h30   | Model Application form as part of module 1?<br>Options for alignment: proposal      | M. Utom (tbc)<br>N. Dellepiane |
| <b>Part 3</b>   | <b>Options for alignment</b>  |                                |
| 15h30- 15h45  | Coffee break  |                                |
| 15h45 - 17h00   | WHO proposed module 1 for PQ submissions  | N. Dellepiane                  |
| 17h00 - 17h30   | General Discussion  | All                            |

**Day 4, Thursday 22<sup>nd</sup> March CTD session  
Hosted by DCVMN at Novotel**

| Schedule              | Topic  | Speaker                  |
|-----------------------|--|--------------------------|
| <b>Part 4</b>         | <b>Countries' experience</b>   |                          |
| 8h30 - 9h30           | Experience of Chinese manufacturers in building a CTD for registration in other countries                | CNBG & Wendy Huong (tbc) |
| 9h30 - 10h00          | BioFarma experience with ASEAN CTD   | Iin Susanti              |
| 10h00 -10h30          | Experience of Indian manufacturers in construction of CTD for Indian NRA and PAHO countries              | Nirav Chokshi (tbc)      |
| 10h30-10h45           | Coffee break   |                          |
| <b>Part 5</b>         | <b>Group exercises</b>   |                          |
| 10h45 – 11h00         | Groups' organization   | S. Pagliusi              |
| 11h00 – 13h00         | Building a CTD<br>WG1: Module 1 and application form<br>WG2: Module 3<br>WG3: Module 4<br>WG 4: Module 5 | Working Groups           |
| Working 13h00 - 14h00 | Lunch  |                          |
| 14h00 - 15h30         | Building a CTD (continued)   | Working Groups           |
| 15h30 - 15h45         | Coffee break   |                          |
| 15h45- 17h00          | Presentation of results by each working group (10 mins)  | Working Groups           |
| 17h00 - 17h30         | Conclusions & Adjourn  | S. Pagliusi              |