



Quality Management Systems

Training for professionals of the vaccine industry

In cooperation with Instituto Butantan – Sao Paulo - Brazil

Day 1 – Monday 24 November 2014

Train-the-trainers approach - Duration: 4 hs.

2 p.m. Welcome and Introductions: New DCVMN Initiatives

3 p.m. Adults training management

1. Learning in Adults. Learning Styles.
2. Characteristics of participants. Depending of background and working areas
3. Techniques to promote participation.
4. Strategies to generate enthusiasm and motivation: exercises and team activities.
5. Development activities focused on learning.
6. Training techniques
7. Dealing with difficult audiences.

4 p.m. Trainer - Facilitator Skills development

1. Effective Communication. Expression.
2. Active listening.
3. Using powerful questions.

5 p.m. How to Plan and Conduct a Training: Documents.

1. Knowing the audience and audience and Company needs.
2. Development of content and structure of the Training Plan and Program.
3. Design of training sessions.
4. Evaluation techniques.
5. Trainee's qualification.
6. Documents in the training process.
7. Exercise: "Aseptic techniques: do's and don'ts"

Questions& Answers.

Day 2 – Tuesday 25 November 2014

Quality Risk Management - Duration 9 hs.

8 a.m.

1. ICH Q9 Regulation "Quality Risk Management" and relation with ICH Q10 Quality Systems: what is expected?
2. Tools in risk analysis:

3. Classification
4. When apply each type?

12.30 p.m. Lunch break

5. How to build a probability, severity, detectability table
6. Practical Exercises: team working approach for:
 - a. Media fill risk assessment
 - b. WFI generation and distribution system

Questions & Answers.

Day 3 – Wednesday 26 November 2014

Deviation Management - Duration 9 hs.

8 a.m.

1. Worldwide Regulatory Requirements
2. Deviations / Incidents / Observations / OOS (out of specifications) / OOT (out of trends) / OOE (out of expectations) / complaints – what can go wrong in vaccines supply chain and how to manage it?
3. Root Cause Analyses tools.

12:30 p.m. Lunch Break

4. Corrective Actions vs CAPA Plan.
5. Root Cause Analyses : practical exercises:
 - a. Deviation in vaccine filling
 - b. Deviation in storage and transport conditions of materials in vaccines formulation
 - c. OOS in WFI
 - d. Vaccines Supply chain complaint: broken vials

Questions & Answers.

Attendants Evaluation.

Day 4 – 27 November 2014

WHO Prequalification – 8 hrs

8 am to 5 pm.

Content to be disseminated soon after consultation with WHO.

Objectives:

After training participants will be able to:

- become aware of their level of development as coaches and facilitators and identify the gap to work in training activities in their Companies
- know the characteristics of adult learning to lead a workout or training
- understand the impact on learning outcomes
- apply presentation techniques that facilitate the learning of any type of adult audience
- acquire and apply techniques that promote motivation and commitment to their students
- understand the steps required for the design and management of a training program and manage a seminar or conference.
- understand the approach of the Quality Risk Management in vaccines manufacturing
- know their level of knowledge in Quality Risk Management
- know how to decide the best tool of Quality Risk Management in vaccines manufacturing
- understand and apply in the practice a risk analysis
- understand the Quality System expectations in deviation, complaints, OOS, OOT, OOE management
- know their level of knowledge in in deviation, complaints, OOS, OOT, OOE management
- know how to decide the best tool for analyzing different King of non-conformities in vaccines supply chain
- understand and apply in the practice in deviation, complaints, OOS, OOT, OOE management
- understand WHO prequalification goals, procedures, requirements, dossier and timelines.