Cost-effective Purification of Vaccines, Data Integrity Systems and CTDs

DRAFT AGENDA

Rio de Janeiro, 18 to 20 June 2018

DAY1, Monday 18 June - Welcome & Introduction Plenary session for all participants hosted by Alfa Wassermann		
Time	Topic	Speaker
8h30 – 9h00	registrations	BioM
9h00 – 9h30	Welcome & Introductions	Host & DCVMN
9h30 – 10h30	Processing of Viral Vaccines: Scale up of centrifugation processes vaccines	S. Merino Alfa Wassermann
10h30 – 10h45	Coffee break	
10h30 – 11h30	Group exercise	AW
11h30 – 13h00	Groups feedback and discussion	AW
13h00 – 14h00	Lunch	
Cost-effective biosafety tools Plenary session for all participants Hosted by Bausch+Stroebel		
14h00 – 15h00	History of ICH: The Common Technical Document, Structure and Contents	N. Dellepiane
15h00 – 16h00	CTD adoption in emerging countries: ANVISA perspectives	A.Araujo/ Lowande/ Marino
15h30 – 16h00	Coffee Break	
16h00 – 17h00	Q&A and discussion	Participants

Session A: Common Technical Document (CTD) training held at Othon, hosted by DCVMN

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

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

DAY2, Tuesday 19th June – CTD session Hosted by DCVMN at Othon		
Schedule	**Topic**	**Speaker**
Part 1	**ICH and Common Technical Document**	
9h00 – 10h00	Contents and Structure of different CTDs	N. Dellepiane
10h00 – 10h30	Q & A	All
10h30 – 10h45	Coffee break	
Part 2	**Comparison of different CTDs**	
10h45 – 11h30	Results of comparative study on similarities and differences between different CTDs	N. Dellepiane
11h30 – 12h30	Q&A and Discussion	N. Dellepiane
12h30 – 13h30	Lunch	All
Part 2	**Comparison of different CTDs(continued)**	
13h30 – 15h00	Other differences that affect the registration procedures.	N. Dellepiane
15h00 – 15h30	Group exercise explanation. Organisation of working groups	S. Pagliusi
Part 3	**Options for alignment**	
15h30 – 15h45	Coffee break	
15h45 – 17h00	WHO proposed module 1 for PQ submissions	N. Dellepiane
17h00 – 17h30	General Discussion	All

Day 3, Wednesday 20nd March CTD session Hosted by DCVMN at Othon		
Schedule	Topic	Speaker
Part 4	**Countries' experiences**	
8h30 – 9h30	BioM experience with CTD	Monique Moraes
9h30 – 10h30	Experience of Argentinian manufacturers in building a dossier for PAHO countries	TBC
10h30 – 10h45	Coffee break	
Part 5	**Group exercises**	
10h45 – 11h00	Groups' organization	S. Pagliusi
11h00 – 13h00	Building a CTD The working groups will be company specific. Manufacturers are invited to bring their own data for a vaccine submission.	Working Groups
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

Session A: Good Documentation Practices and Data Integrity, held at Othon, hosted by DCVMN

Objectives:

during biological and pharmaceutical manufacturing, control, distribution chain, many documents are part of the GXP. The application of Good Documentation Practices and Data Integrity, as part of the QMS and based on QRM are more than requirements, as EMA enounces “the key for public health”.
Course description:
For many years we follow established regulatory guidelines, nevertheless, poor documentation practice is still happens and has become a global problem that may lead to severe violations of data integrity principles that affects quality, safety and efficacy of products.

Participants:

Senior Professionals working on vaccine manufacturing, Quality Control and R&D responsible, corporate Quality Assurance, international qualification and registration of products and training of staff.

Expected Outcomes:

This course will offer deep awareness of good management of Industry good documentation practice among the whole manufacturing chain. At the end of this workshop, participants should be able to establish a robust and transparent documentation process, make it highly reproducible and sustainable for their institutions, and know how to define risks to avoid.

DAY2, Tuesday 19th June – Data Integrity session Hosted by DCVMN at Othon		
Schedule	**Topic**	**Speaker**
8h30 – 9h00	Welcome and introductions	
9h00 – 10h00	Data Integrity Principles: ALCOA How to ensure data record, traceability, integrity Bases of Good documentation practices and Data Integrity Guidelines	S. Rumiano
10h00 – 10h15	Coffee break	
10h15 – 11h15	Implementation of Data Integrity Standards at your Site The GMP Document Roadmap: Implementation model based on Quality Risk Management	S.Rumiano
11h30 – 12h30	Data process maps for paper and hybrid process	S.Rumiano
12h30 – 13h30	Lunch	All
13h30 – 14h30	Exercise: road map: general	
14h30 – 15h30	Pre-requisites: data integrity policy with effective training Identifying risk to records and mitigating them How to train staff in Good Documentation Practice and Data Integrity Control of Templates and Blank Forms Common pitfalls	
15h30 – 15h45	Coffee break	
15h45 – 17h00	Practical Exercises : follow up in Production and QC	
17h00 – 17h30	General Discussion	All

Day 3, Wednesday 20nd March CTD session Hosted by DCVMN at Othon		
Schedule	Topic	Speaker
8h30 – 9h30	Inspectors expectations on industry from different authorities: FDA, ANVISA, EMA, MHRA, WHO Typical documentation failures and how to avoid them – key learning points	
9h30 – 10h30	Detection of poor documentation practices and falsification Audit Trail Review / Log File Review How to establish a compliant and under control process Document inventory and reconciliation: archiving and recovery GMP requirements vs. Knowledge Management	
10h30 – 10h45	Coffee break	
10h45 – 11h45	Exercise: BR review: traceability and data integrity	
11h00 – 13h00	Records – Life Cycle and data integrity issues GMP Record Lifecycle Control Mechanisms	
13h00 – 14h00	Lunch	
14h00 – 15h30	Exercise: internal audit process practice	Working Groups
15h30 – 15h45	Coffee break	
15h45 – 17h00	Presentation of results by each working group (10 mins)	Working Groups
17h00 – 17h30	Conclusions & Adjourn	