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**Meeting Report**

**WHO Workshop on Implementation of Good Manufacturing Practices (GMP) for  
Biological Products**

**Seoul, Republic of Korea**

**19-21 September 2018**



## Introduction

The World Health Organization (WHO) Workshop on Implementation of Good Manufacturing Practices (GMP) for Biological Products was convened from 19 to 21 September 2018, in Seoul, Republic of Korea.

Participants in the workshop included the representatives from National Regulatory Authorities (NRAs) of vaccine producing countries: Bangladesh, Bulgaria, Indonesia, Iran, Kazakhstan, Republic of Korea, Russia, Thailand, and Vietnam. In addition, two representatives of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and few other representatives of Korean biological products manufacturers participated in the workshop. The workshop was opened by Dr Kyung Won Seo (Director General of Pharmaceutical and Medical Device Research Department, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety), who welcomed the participants to Seoul and wished them a successful, productive and interactive workshop. The workshop was chaired by Mr Victor Maqueda with two rapporteurs: Dr Anil Kumar Chawla and Mr Mohamed Refaat.

After the introduction of the participants and facilitators, Dr Dianliang Lei (WHO) made a presentation on the workshop objectives and expected outcomes. In his presentation, Dr Lei reminded the participants that, as called by WHO constitution, development, establishment and promotion of international standards with respect to biological and pharmaceutical products is one of WHO's core business which has been excelled over the last 60 years. The three areas where WHO extensively worked to implement the aforementioned function include global written standards, global measurement standards and scientific advice. In addition, Dr Lei updated the participants on WHO priorities of work; organization, functions and activities of WHO's Cluster of Access to Medicines, Vaccines and Pharmaceuticals (MVP) as well as strategic plan of WHO's Department of Regulation of Medicines and other Health Technologies (RHT). Finally, Dr Lei concluded the introduction with the workshop objectives and expected outcomes. The objectives of the workshop were: 1. to better understand current practices of GMP inspection in the participating countries; 2. to familiarise NRAs and vaccine manufacturers with the contents of WHO GMP for biological products and to clarify any issues that may interfere with the implementation of the principles of WHO GMP into their regulatory practice; and 3. to identify any potential needs for further guidance on GMP inspection and other relevant regulatory activities. At the end of the workshop it was expected that: 1. participants will have a better understanding of the key principles and expectations of an effective GMP inspection system; 2. participants will identify the current gaps in their GMP inspection system and how to move forward with improvement; and 3. the workshop will provide a forum for regulators and manufacturers to build confidence on collaborations for implementation of GMPs in manufacturers.

Mr Victor Maqueda gave an introductory presentation on the main principles of WHO GMP. In his presentation, Mr. Maqueda focused on the identification of main milestones for the development and progress of GMP guidelines and clarifying the relationship between GMP and other quality subjects (e.g. QMS, PQS, QRM, QC). His presentation outlined the tragic incidents of the 20<sup>th</sup> Century which contributed to the birth and development of GMP which included contamination of diphtheria toxoid with tetanus toxin (1901), Death elixir (1937), Sulfathiazole tablets (1941), Cutter incident (1955), Thalidomide tragedy (1960s), Devonport incident (1972) and contaminated heparin (2008). Mr Maqueda clarified the definition of GMP, its building blocks and quality relationship. Mr Maqueda concluded his presentation by listing essential elements of WHO basic GMP as well as GMP for biological products with worldwide focus on quality risk management (QRM) thinking and considerations.

Representatives of each participating country gave a brief presentation of the current situation of implementation of GMP in their respective countries with focus on:

1. current GMP guidelines followed in the country,
2. key differences between WHO GMP and the respective country GMP,
3. issues/problems encountered during GMP inspections,
4. respective country expectations from WHO, and
5. efforts made by the NRA in last year to improve the maturity for GMP inspections.

In summary, some countries are following WHO GMP Guidelines including GMP for biological products in whole or in principle. Some countries are following EU GMP or PIC/S GMP or own national GMP guidelines. The comparison between different GMPs showed that WHO guidelines contains some specific sections on pharmaceuticals quality system & quality risk management, containment, campaign production, labeling and validation which are highly useful to manufacturers and regulators. The main GMP issues encountered by GMP inspectors of participating countries, include computer system validation, audit trail, equipment and machines recalibration, lack of documentation of key personnel qualification, suitable facility design, movement and mix up of personnel, measures in-place for prevention of cross-contamination, organizational control (campaign processing, cleaning verification etc.), robust process for the formalized quality risk management of cross-contamination, risk assessment – Risk Priority Number (RPN) not properly calculated, documentation compliance and staff turnover issues, and classification of identified deficiencies. There is a need from participating countries to develop knowledge of inspectors on master cell banking along with their characterization, downstream & upstream processing, and process validation etc. Trainings organized by WHO in the above mention topics are highly requested.

The IFPMA representative provided a presentation on the industries' perspectives on WHO GMP implementation. The presentation was made on behalf of the IFPMA Regulatory Science Committee (RSC) & Vaccine Scientific Regulatory Work Group (VSRWG). IFPMA applauds to WHO for the revision of guideline on GMP for Biologics. As a matter of fact, the recent WHO GMP Guidelines for biological products is expected to advance regulatory convergence and cooperation at regional and international level and also to enhance access to medicines. Experience and lessons learnt in implementation of WHO GMP Guidelines include:

- GMP standards and associated inspections are important components of strong regulatory systems, and contribute to ensuring that pharmaceutical products are manufactured to high quality standards;
- IFPMA supports programmes by WHO, ICH and PIC/S to develop common standards, harmonize the interpretation and inspection, and to promote convergence of GMP standards;
- industry encourages opportunities for evidence-based discussions on emerging regulations and interpretation;
- IFPMA proposes approaches on GMP standard convergence, aligned inspection processes, and NRA cooperation.

Dr Dianliang Lei presented an overview of the revision of WHO GMP for Biologicals. In his presentation, Dr Lei provided a background on the WHO GMP guidelines for biological products being an annex to the WHO GMP for pharmaceutical products: main principles. The guidelines are widely used or adopted by regulators and stakeholders. It is mandatory guidelines for WHO medicine and vaccine prequalification programmes. There was a strong request from WHO Member States for revision and update of GMP for biological products. The revision process was explored in 2007 and continued in 2013 with a drafting group meeting. The revised document was finalized after public consultation and approval by the WHO Expert Committee on Biological Standardization (ECBS) and the Expert Committee on Specification for Pharmaceutical Products (ECSP) in October 2018. The drafting group faced many challenges with the Guidelines including definition of biological products, keeping the balance to give orientation on strategy and focus of requirements for biological products without detailing "how-to-do" and to consider vaccines and other biological products at par. The general principles which guided the drafting group included the focus on special considerations to biological products (e.g. QC, biosafety/bio-containment, environment monitoring, production and campaign production, use of animal, starting materials (seed lot/cell bank), quality risk assessment, QMS). The sections of the revised guidelines were expanded (when compared to the old guidelines) by inclusion of new sections for terminology, pharmaceutical quality system and quality risk management, starting materials, seed lot and cell bank, containment, cleanrooms, campaign production and validation. The key changes introduced in the revised guidelines were clarified with

respect to scope, general considerations, cell bank and seed lot systems, personnel, reference and retention samples, premises, production, campaign production, containment, validation, use of animals, and documentation.

Mr Mustapha Chafai, WHO prequalification team, presented his experience on on-site audit for the purpose of vaccine prequalification. In his presentation, Mr Chafai provided background on the WHO inspection process including the structure of the WHO PQT, types of WHO inspections, the related norms, standards and guidelines (including the revised WHO GMP guidelines for biological products) used in inspection activities to ensure wide applicability used for inspections. Mr Chafai clarified the possible outcomes of a WHO inspection which include (1) conclusion of compliance with GMP and subsequent acceptability when there are "other" deficiencies only; (2) conclusion of compliance after the corrective and preventive actions (CAPAs) have been positively assessed when there are "other" and a few "major" deficiencies; and (3) conclusion of non-compliance with GMP when there are critical or several major deficiencies. Serious non-compliance can lead to notice of concern, notice of suspension and/or delisting. Mr Chafai summarized common deficiencies observed during inspections which comes under several subjects including Quality Risk Management, Product Quality Review, Good data and records management, Facility and Equipment, Environmental monitoring, Production, Starting Materials especially Biological Origins, Seed lots, Personnel, Deviations and Investigations into root cause analysis. Several examples were given for deficiencies of each of the above mentioned subjects. Mr Chafai concluded his presentation with some worrying and promising trends. Worrying trends include critical deficiencies related to data integrity, high number of raised major and other deficiencies, many "await CAPA" inspections with poor root cause investigation, and initial hard work to pass first inspection and then forgetting that compliance is an ongoing process. Promising trends on the other side include strong commitment from senior management to always seek compliance, increasing knowledge of the requirements and the regulatory expectations, increasing knowledge of the products and the manufacturing processes and the control stages, increasing cooperation with country inspectorates and improvement of GMP implementation.

Mr Mohamed Refaat (WHO consultant) presented an update on the revision of Pharmaceutical Quality System (PQS) and Quality Risk Management (QRM) section of the Guidelines. For each of the concerned sections, the presenter made a comparison between the recommendations of the old versus the revised guidelines. In his presentation, Mr Refaat provided a review of changes/update in GMP guidelines for biological products with respect to PQS and QRM with highlights on the guidance provided under the above listed chapters. Mr Refaat stressed the fact that consistency is especially key for biological products given their inherent variability. WHO expectations to achieve consistency for biological products include manufacturing in accordance with the requirements of a PQS based on a life-cycle approach as defined in WHO GMP main principles with special focus on the link between development and manufacturing, validation, change control, CAPA, product quality review

along with trend analysis and continual improvement and innovation. For simplification purpose, Mr Refaat showed the diagram of the ICH Q10 Pharmaceutical Quality System Model. In addition, Mr Refaat stressed on the fact that the revised WHO GMP guidelines for biological products took QRM principles into full consideration across the whole guide. In addition to a dedicated section of QRM (as an enabler of PQS), extensive guidance is provided throughout the guidelines. Indeed, the word “risk” is amongst the most repeated words in the document. Mr Refaat guided the participants through the QRM process starting with risk assessment, through risk control and risk review along with risk communication and risk management tools. Mr Refaat concluded his presentation by providing clarification of Failure Mode Effects Analysis (FMEA) as one of most famous and frequently used QRM tools.

Mr Refaat presented the first case study of the workshop discussing QRM of manufacturing process of biological products. The case study was a practical exercise for the participants on applying QRM, and particularly FMEA, for the inactivation process of a viral vaccine. After explanation of the essential background information of the case study, each of the four groups of participants were asked to read, discuss the case study and present the conclusion of their discussions. The outcomes of discussions of the working groups were presented in a role play where two groups assumed the role of manufacturer while the two other groups assumed the role of inspectorate.

The revision of GMP for biological products with regards to sections on personnel, starting materials, seed lot, and cell bank system was given by Mr Maqueda. He highlighted the particularities of biological products with respect to their inherent variability and how biological products differ from conventional/chemical medical products. Mr Maqueda also clarified that the scope of the revised WHO GMP guideline for biological products remained the same as the earlier version with exclusion of whole blood, blood products and plasma derived products; and in-vitro diagnostics while in-vivo diagnostics and Advanced Therapy Medicinal Products (ATMP) were included. The scope and extent of the application of the revised GMP guidelines were also explained for different stages of manufacturing of biological products. For each of the concerned section, the presenter made a comparison between the recommendations of the old versus the revised guidelines. For the personnel section, different recommendations with respect to competence, health status, and movement restriction as well as special recommendations for personnel working on BCG production were discussed. Similarly, for starting materials, control of sources and suppliers, supply chain, sampling and testing were clarified. Finally, recommendations for seed lots and cell banking systems were explained.

The second case study focused on risk assessment of cell bank system-preparation. Similar to the first case study, participants were asked to read, understand and discuss the case study amongst

their four groups. This case study was built upon the first one and the participants successfully implemented QRM principles for another critical stage of the manufacturing process.

The revision of the premise, equipment, cleanroom and containment sections was updated by Dr Chawla. For each of the concerned sections, the presenter made a comparison between the recommendations of the old versus the revised guidelines. Dr Chawla provided several examples of the encouraged state of the art technologies for premises and equipment used for the production of biological products including disposable and closed systems. Also, measures for containment purpose were clarified including those related to personnel, utilities (including heating, ventilation and air conditioning "HVAC" systems), equipment, and waste management along with good practices (e.g. good microbiological practices, and good waste management).

Dr Chawla also led the discussion on the third case study related to risk-based facility design. The participants were provided with two layouts of tetanus bulk production facilities. The first layout contained several critical deficiencies including risk of contamination of non-live from live areas while the second layout was almost ideal. Participants were asked to review the layouts and identify any deficiencies and they managed to do so in an effective way.

The last day of the workshop started with a presentation from Mr Mohamed Refaat with an update of the revision of the production and campaign production sections. For both sections, the presenter made a comparison between the recommendations of the old versus the revised Guidelines.

Mr Refaat briefly explained the recommendation for the production of biological products with an example process flow for production of vaccines. In addition, Mr Refaat clarified the recommendation for campaign production along with the essential need for QRM approach to justify the multi-product/shared facilities.

The fourth case study was also presented by Mr Refaat. The case study related to Multi-Product Facility and Campaign Production. The case study was introduced to the participants as a manufacturer who was willing to use a single filling line for filling of polysaccharide vaccine with human insulin. Role play was again considered with two participants' groups playing the role of the manufacturer and the other two groups playing the role of the inspectorate. The participants perfectly identified the key areas of concern with respect to this case study which related to QRM exercise to justify the shared facility.

Dr Anil Chawla presented an update on the revision of quality control (QC), use of animals and documentation sections. Similar to all other sections, Dr. Chawla started his presentation with a comparison between the old and the revised Guidelines for the specified sections. In his presentation,

Dr Chawla explained the quality relationship between QC, GMP, Quality Assurance (QA) and Quality Management System (QMS or PQS). In addition, the sample for post release testing including reference and retention samples were explained. Recommendations with regards to the use of animals along with animal husbandry were clarified. Finally, labelling and documentation recommendations were explained.

The revision of the validation section was presented by Mr Maqueda. Mr Maqueda stressed on the fact that this section, similar to few other sections, is new in the revised Guidelines and no comparable section could be found in the old Guidelines. CPP, CQA, process validation and revalidation, review of trends and deviations, and change control were briefly discussed and inter-linked to each other.

The fifth case study was also facilitated by Mr Maqueda and it focused on process validation of vaccine inactivation process. Participants were asked to use a qualitative risk assessment method to identify and rank different risks associated with the mentioned stage of vaccine production.

Before close of the workshop, each participant was asked to provide written feedback on the workshop. In summary, the feedback were very positive. The presentations and case studies were highly valued and appreciated by the participants. Regarding the length of the workshop, the balance between presentation and discussion, and the balance between presentations and case studies, the majority of feedback from participants was about right. The information of presentations by facilitators was clear. Points to be improved for future workshops were suggested in the following area: A day only addresses one topic so it will be more focused; Pay more attention to practical aspects/observations from real inspection; Evaluation of suppliers, Skill of inspection; For the case study, it will be better if the facilitator gives more time and summarize the critical points; Tasks should be more variable. Most of them were quite similar; skills of inspection.

It was suggested the following topics may be included in future workshops: 1) Production of specific products such as conjugated vaccines and related concerns, biosimilars and biotherapeutics, radiopharmaceuticals, human blood or plasma derived products etc.; 2) Validation considerations especially computer validation; 3) Use of computerized system; 4) Design of facility and quality by design principles; 5) Quality risk management and tools for QRM; 6) QC, e.g. microbiological lab, microbiological testing; use animal for testing; 7) Data integrity; 8) Biosafety handling compares with GMP; 9) Environment monitoring plus case study; 10) Aseptic filling.

It was suggested by participants that it would be better prepared by the participants if the presentation materials could be provided before the workshop. The successful organization of the workshop by MFDS and the hospitality of the organizer were highly appreciated by all participants and facilitators.



The content of the workshop was very informative and relevant to their work. Participation would benefit the implementation of WHO GMP for biological products and improve GMP inspection in their country.

By this second workshop the slide presentations and case studies have been practiced twice and will be finalized and ready for future use.

### **Authors**

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On behalf of the WHO workshop on implementation of GMP for biological products.

## Appendix 1: List of Participants

### Facilitators:

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## Appendix 2: Workshop agenda

WHO Workshop on Implementation of GMP for Biological Products

Seoul, Republic of Korea, 19-21 September 2018

### AGENDA

Chairman: Victor maqueda

Rapporteur: Anil Chawla and Mohamed Refaat

### Day 1, Wednesday 19 September 2018

#### Session I Opening of the meeting

09:00-09:15	Opening Remarks	WHO and MFDS
	Introduction	All participants
09:15-09:30	Objectives and expected outcomes of the meeting	D Lei
09:30-09:40	Group photo	All
09:40-10:10	WHO GMP main principles	V Maqueda
10:10-10:30	Coffee break	

#### Session II Current approaches of GMP for biologicals

10:30-12:30	Current practices of GMP for biological products of selected participating countries (10 min. each)	
	Bangladesh, Bulgaria, Indonesia, Iran, Kazakhstan, Korea, Republic, Russia, Thailand and Vietnam	
	Industry's perspectives on GMP (20 min.)	IFPMA

12:30-13:30 Lunch Break

#### Session III: WHO Guidelines on GMP for biological products

13:30-13:45	Overview of revision of WHO GMP for Biologicals	D Lei
13:45-14:15	PQ experience on on-site audit	M Chafai

14:15-14:45	<b>Presentation:</b> Update the revision of GMP for biologicals: Personnel, starting materials, seed lot, cell bank system	V Maqueda
14:45-15:30	<b>Case study 1:</b> MCB/WCB system	V Maqueda and all facilitators
15:30-16:00	Coffee Break	
16:00-17:30	<b>Case study 1:</b> MCB/WCB system (cont'd)	
17:30	Closure of the day	

## Day 2, Thursday 20 September 2018

09:00-09:30	<b>Presentation:</b> Update revision: PQS and QRM	M Refaat
09:30-10:30	<b>Case study 2:</b> QRM of manufacturing process of biologicals	M Refaat and all facilitators
10:30-11:00	Coffee break	
11:00-12:30	<b>Case study 2:</b> QRM of manufacturing process of biologicals (cont'd)	
12:30-13:30	Lunch break	
13:30-14:00	<b>Presentation:</b> Update revision: Premise, clean room and containment	A Chawla
14:00-15:30	<b>Case study 3:</b> Facility design	A Chawla and all facilitators
15:30-16:00	Coffee break	
16:00-17:30	<b>Case study 3:</b> Facility design (cont'd)	
17:30	Closure of the day	

## Day 3, Friday 21 September 2018

09:00-09:30	<b>Presentation:</b> Update revision: production and campaign production	M Refaat
09:30-10:30	<b>Case study 4:</b> multi-products facility	M Refaat and all facilitators
10:30-11:00	Coffee break	

11:00-12:00 **Case study 4:** multi-products facility (cont'd)

12:00-12:30 Presentation: Update revision: QC, use of animals and documentation

A Chawla

12:30-13:30 Lunch break

13:30-15:30 **Presentation and Case Study 5:** Process validation

V Maqueda and all facilitators

15:30-16:00 Coffee Break

**Session IV Networking for implementation of GMP for biologicals**

16:00-17:00 Round table discussion on implementation of GMP Participants and facilitators

17:00-17:30 Feedback on the workshop

Participants

17:30 **Closing of the meeting**