World Health Organization

Draft Agenda

Workshop with the International Generic and Biosimilar Medicines Association (IGBA) on Collaborative Registration Procedure (CRP) for generics and biosimilars prequalified by WHO and SRA approved (in-person and virtual)

Date : 05 July 2023 (9-12h CET)

Venue: WHO HQ office (room TBC)

Moderator: Unit Head, Regulation and Safety, Department of Regulation and Prequalification (RPQ)

Time	**Agenda**	**Responsible**
09:00 – 09:20	Welcome remarks Overview of the workshop objectives and agenda	Director RPQ, WHO
09:20 – 09:45	WHO PQ Medicines and Biotherapeutics programme and sharing of PQ assessment reports to enable CRP	Team Lead, RPQ/PQT WHO
09:45 – 10:15	Overview of Collaborative Registration Procedure: progress in implementation and identified challenges	Team Lead, RPQ/REG/FPI WHO
10:15 – 10:45	Coffee Break	
10:45 – 11:20	• Industry experience with the implementation of CRP for generics and biosimilars prequalified by WHO and approved by SRAs • Challenges experienced by industry with the implementation of CRP for generics and biosimilars prequalified by WHO and approved by SRAs	IGBA
11:20 – 11:50	Plenary discussion and recommendations to overcome the challenges identified	ALL
11:50 - 12:00	Conclusions and close of the Workshop	Director RPQ, WHO