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Developing Countries Vaccine Manufacturers Network

Draft Agenda for regional QMS Workshop.

Changes and Variations Management and Biosafety Testing of Vaccines for the Global Market

15th November 2013, New Delhi, India

For professionals working in the vaccine manufacturing industry

Agenda item	**Speaker**	**Suggested Start time**
Introductions and Review of Agenda Perspectives of manufacturers on product profile	Dr. R. Suri	09:00am
WHO new guidelines on post-approval changes and variations management of vaccines	Dr. D. Lei	09:30am
Coffee break		10:30am
Sharing experiences on Practical aspects and case studies in changes & variations management	Dr. D. Lei	11:00am
Q&A discussion		12:00pm
Networking lunch		12:30pm
Vaccine monographs and regulatory guidelines • Focus on WHO requirements. • FDA and EMEA requirements. • Latest developments and Stability testing	Dr. Martin Wisher	1:30pm
Biosafety testing strategy for WHO market • Master and Working Cell Bank Characterisation. • Master and Working Virus Seed Characterisation. • Emerging virus threats. • Oncogenicity, tumourigenicity and latent viruses. • Pitfalls to avoid.	Dr. Martin Wisher	2:15pm
Coffee break		3:00pm
New technologies in vaccine manufacturing	Dr Detlef Heep	3:30pm
Disposable technology improving cost-effectiveness of manufacturing	Dr. C. Fegel	4:15pm
Conclusions and close	Dr. Suri	05.00pm