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Maintaining the Quality of Vaccines Through the Use of Standards: Current Challenges and Future Opportunities

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Dr Dianliang Lei received his doctor degree in medical science from Medical School of Osaka University Japan in 1996. He joined World Health Organization in 2003 as a scientist working in Technical Specifications and Standards unit of Health Product Policy and Standards department, responsible for development of WHO international standards including measurement standards and written standards for vaccines and biological products. He has been in charge of development of WHO Guidelines for lot release of vaccines, GMP for biological products, Guidelines for post-approval changes to vaccines, Guidelines for marketing authorization of pandemic vaccines in importing countries, Recommendations for acellular pertussis vaccines, DT-based combined vaccines, Hepatitis E vaccines, Enterovirus vaccines, yellow fever vaccines and Manual for calibration of secondary standards. Dr Lei, before joining WHO, was deputy director of National Institute for the Control of Pharmaceutical and Biological Products responsible for regulation, quality control and biological standardization of vaccines in China. He contributed to the strengthen the regulation system for vaccines in China, especially on the national requirements (pharmacopeia) for biologicals, standards, specification for vaccines and lot release system.