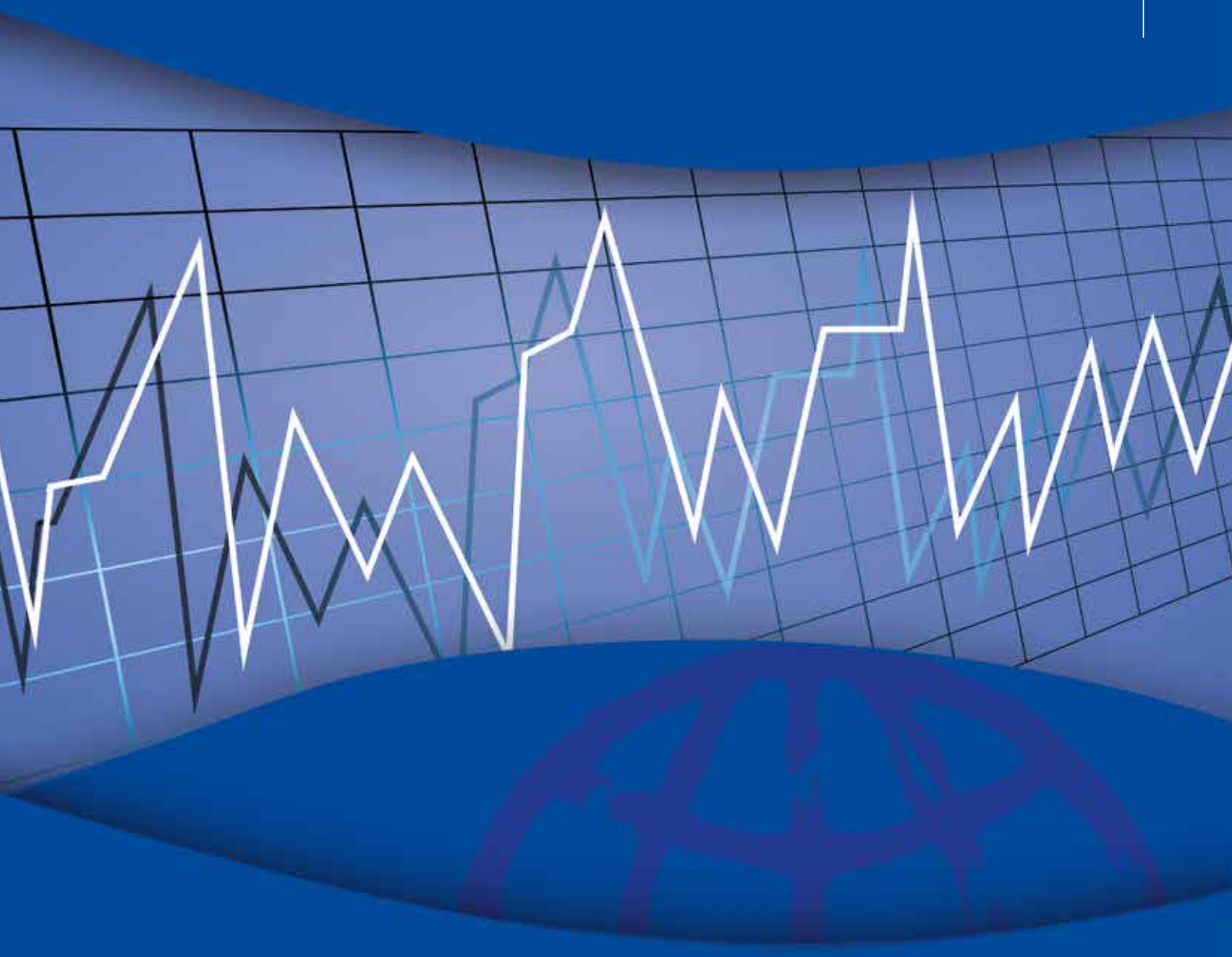
World Health Organization

POST-MARKET SURVEILLANCE OF IN VITRO DIAGNOSTICS



World Health Organization

POST-MARKET SURVEILLANCE OF IN VITRO DIAGNOSTICS

WHO Post-market surveillance of in vitro diagnostics

WHO Library Cataloguing-in-Publication Data

Post-market surveillance of in vitro diagnostics.

1.In Vitro Techniques. 2.Product Surveillance, Postmarketing. 3.Equipment Safety. 4.Equipment Failure. I.World Health Organization.

ISBN 978 92 4 150921 3 (NLM Classification: WA 289)

Printed in France

Contact:

Irena Prat, Essential Medicines and Health Products - WHO - 20, Avenue Appia - 1211 Geneva 27- Switzerland

This document is available on the internet at: www.who.int/diagnostics_laboratory/en/

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACKNOWLEDGEMENTS

The following people were part of the technical working group who met in Geneva on two occasions (June and October 2014) to develop the guidance. This guidance document was written by Anita Sands and Irena Prat, with overall direction by Irena Prat. Monika Zweygarth provided editorial and layout assistance.

The experts who participated in two rounds of consultative meetings (June 2014 and October 2014) and reviewed the draft guidance were: Sue Best, Patience Dabula, Joelle Daviaud, Dianna Edgil, Martine Guillerm, Jan Jacobs, Deidre Healy, Sandra Incardona, Joel Kuritsky, Victor Muchunguzi, Heiner Scheiblauer, Aisseta Tourè, Elsa Tran, Stuart Turner, Vincent Wong, and Bibiana Zambrano.

The draft guidance was then made available for public comment on the WHO website for the period of one month in early 2015.

The WHO staff who participated in the development and review of the guidance were: Helena Ardura, Jane Cunningham, Shona Dalal, Guy-Michel Gershey-Damet , Cheryl Johnson, Robyn Meurant, Irena Prat, Sabine Ohse, Julie Samuelson, Anita Sands and Willy Urassa.

DISCLAIMER

This guidance was developed based on the in vitro diagnostic (IVD) technology in use at the time, and therefore may require certain adaptation as technology formats develop. The illustrative examples used in this guidance are not an exhaustive list.

INTRODUCTION

1. BACKGROUND

Prequalification of IVDs

The World Health Organization (WHO) Prequalification of In Vitro Diagnostics Programme is coordinated through the department of Essential Medicines and Health Products. The aim of the WHO Prequalification of In Vitro Diagnostics Programme is to promote and facilitate access to safe, appropriate and affordable in vitro diagnostics (IVDs) of good quality in an equitable manner. Focus is placed on IVDs for priority diseases and their suitability for use in resource-limited settings.

Comprehensive assessment

The WHO Prequalification of In Vitro Diagnostics Programme undertakes a comprehensive assessment of IVDs through a standardized procedure aimed at determining if the product meets WHO prequalification requirements. The prequalification assessment process includes three components:

- Review of a product dossier;
- Laboratory evaluation of performance and operational characteristics; and
- Manufacturing site(s) inspection.

Beneficiaries

The findings of the WHO Prequalification of In Vitro Diagnostics Programme[1] are used to provide independent technical information on safety, quality and performance of IVDs, principally to other United Nations (UN) agencies but also to WHO Member States and other interested organizations. The WHO prequalification status, in conjunction with other procurement criteria, is used by UN agencies, WHO Member States and other interested organizations to guide their procurement of IVDs.

Post-market surveillance

The purpose of post-market surveillance is to protect individual health and public health through continued surveillance of IVDs once they are placed on the market by reducing any risks. Such activities should ensure the manufacturer's obligations are fulfilled through ensuring they are aware of event which enables them to undertake and assessment of any risks, and as appropriate any suggested steps to risk mitigation.

In the context of the WHO Prequalification of In Vitro Diagnostics Programme, this guidance aims to ensure the ongoing compliance of WHO prequalified IVDs with WHO prequalification requirements once they are placed on the market. Manufacturers of WHO prequalified IVDs are obliged to report regularly post-market information to the relevant national regulatory authorities, and to WHO.

2. SCOPE AND INTENDED AUDIENCE OF THIS GUIDANCE