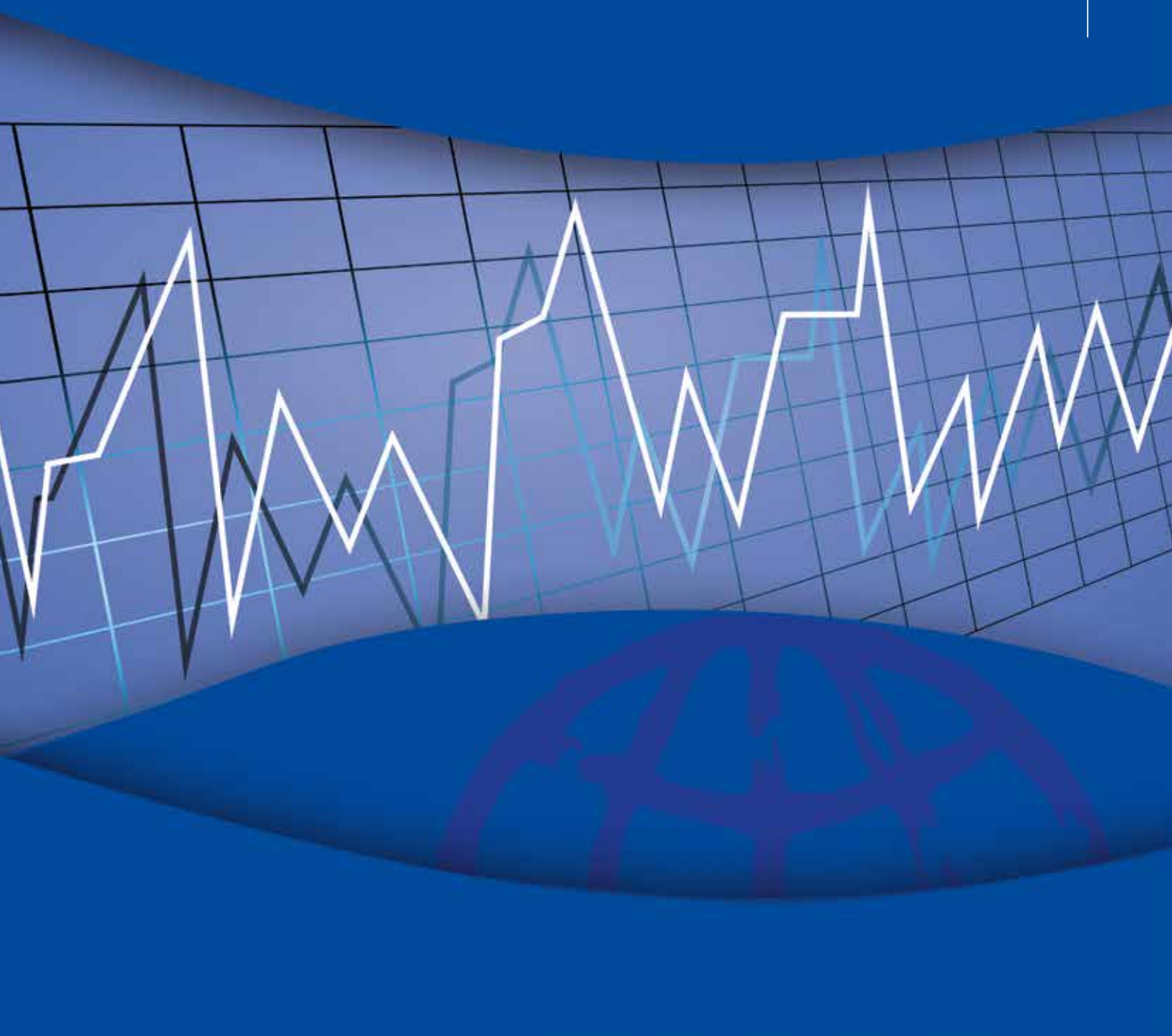


# POST-MARKET SURVEILLANCE OF IN VITRO DIAGNOSTICS

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# 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<sup>1</sup> 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 an 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

预览已结束，完整报告链接和二维码如下：

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