ASPHALION MedTech

Unlocking the power of Precision Medicine

The Journey for ensuring regulatory compliance of Companion Diagnostics (CDx) in Pharma-Medtech nexus

Companion Diagnostics (CDx) are diagnostic tests that are specifically designed to identify patients who are most likely to benefit from a particular therapeutic product. They serve as the bridge between pharmaceuticals and medical devices, ensuring that the right patients receive the right treatment at the right time.

- Immunohistochemistry (IHC)
- Quantitative and qualitative polymerase chain reaction (PCR)
- Next-generation sequencing (NGS) and liquid biopsy
- Fluorescent or chromogenic in-situ hybridisation (FISH/CISH)
- Flow Cytometry

THE CHALLENGE FOR THE PHARMA INDUSTRY OF NOT OVERLOOKING THE IVD COMPONENT IN THEIR THERAPIES DEVELOPMENT!

Emerging synergy of Precision Medicine & CDx

Customizes treatments based on a patient's unique biology, environment, and lifestyle, often using biomarkers.

Companion Diagnostic (CDx) tests are commonly employed to support these personalized treatments.

Role of companion diagnostics

- Identifies patients who will benefit or are at risk of serious adverse reactions.
- Utilizes patients' blood and tissue biomarkers.
- Personalized therapeutic strategies avoiding trial-and-error medicines.

Compliance with IVD regulation 2017/746 for the IVD component

Key Points

- Quality Management Systems
- Revision of Technical Documentation
- Conformity assessment procedures

1. Performance evaluation (PEP & PER)
2. Analytical performance (traceability)
3. Clinical evidence (PMS plan & PMPF as new requirement)

Concerns in EU

- Long Procedure
- Not always at the same time of the drug
- EMA Consultantion by NB (60 days)
- Only a few CDx with CE mark

Challenges

- Data availability
- CDx complexity
- CDx technology novelty

ASPHALION MedTech

KEEP IT SIMPLE AND TRUST THE EXPERTS

By identifying Companion Diagnostics early in your development process, you not only streamline regulatory approvals but also open doors to a more targeted and effective approach to patient care.

With **Asphalion's expertise**, together we will ensure that your path to CDx is fully in compliance with IVD Regulation, empowering you to deliver life-changing treatments to patients.

HOW CAN ASPHALION SUPPORT YOU IN THE DEVELOPMENT OF AN IN VITRO DIAGNOSTIC including CDx?

Pre-market activities

- Regulatory Strategy for CE certification/FDA approval
- Feasibility assestment
- Regulatory Roadmap
- Risk analysis
- Performance Evaluation plan & reports
- Analytical and Clinical Support

Registration

- Selection and approach with Notified Bodies
- Technical Document compilation
- Management of Non-Conformities
- Quality Management System support

Post-market activities

- Post market Surveillance, including Post-market Performance Follow-up
- PSUR and Summary of Safety and Performance (SSP) maintenance
- 1st and 2nd level mock audits
- Periodic Standards Review
- QMS Maintenance

www.asphalion.com
medtech@asphalion.com | +34 93 238 59 45