The importance of early Quality Control, Quality Management and Regulatory Approval considerations for Pharmaceutical and Diagnostic Product development

The pharmaceutical and diagnostic industries are highly regulated, and for good reasons: products need to be safe and effective. Therefore, regulatory approval for product marketing will only be granted, if pharmacological, clinical and other performance studies unambiguously indicate that the medical benefits outweigh residual risks.

Consequently, there is a wealth of international and national laws, regulations, guidelines and standards established and regularly updated. Knowing, following and interpreting these often fast-changing binding rules requires constant monitoring by the pharmaceutical and diagnostic industry of respective regulatory websites.

To give just one example: The European Medical Device Regulation 2017/745 (EU MDR) of the European Parliament and the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, regulates the marketing of medical devices in the EU. It became legally binding on May 26, 2021 (postponed by 1 year due to the Corona pandemic) in all EU member states.

All medical devices registered after that date need to comply with the Regulation EU 2017/745. For some articles of the device, different deadlines apply. For products brought to market before May 25, 2021, the previous directives 90/385/EWG und 93/42/EWG still apply.

There will be exceptions for medical devices already approved. An additional 3-year transitional period is defined to allow manufacturers to place products under the existing certificates on the market. However, special requirements must be met by the products and manufacturers. This additional period will end in May 2024.

The new EU MDR covers 123 articles and 17 annexes. In the EU, this regulation – together with the previous directives – is the major operative instrument to prove effectiveness and efficiency of medical devices in order to receive the CE mark.

Additional examples of similarly complex (or even more complex) regulations exist for in vitro diagnostics and pharmaceutical products, which usually require expanded clinical studies beyond the regulatory requirements of medical devices.

Marketing your product globally requires know how of additional national regulatory requirements. In particular, meeting the US FDA requirements may be challenging.

In addition, product development requires usually the application of international and / or national standards.

For examples, establishing a quality management system for firms in diagnostics requires the application of ISO 9001 and / or ISO 13485; for in vitro diagnostic or medical device product

development the application of at least ISO 14971 (Medical devices –Application of risk management to medical devices), DIN EN 62366 (Medical devices –Application of usability engineering to medical devices), and probably many more will be a “must” (the Notified Bodies will demand this, unless the firm can provide comprehensible ways showing compliance with the EU MDR without applying the standards; “presumption of conformity”).

Quality Assurance Procedures & Specifications need to be developed for the compliant manufacturing of your product, resulting in a Design History File (DHF). Examples of DHF documents may include SOPs (Standard Operating Procedures) and Manufacturing Instructions. A Device Master Record (DMR) is a collection of all documents describing how a product lot was produced.

DHF and DMR are usually reviewed by competent authorities, for example as part of an audit or on-site inspection. The DHF is an essential part of product registration in order to receive the CE mark for the EU market.

Device Specifications, Packaging and Labeling Specifications, Installation and Maintenance & Servicing Procedures and Methods, and Production Process Specifications need to be developed.

Personal experience has shown that large and middle-sized, mature firms in the pharmaceutical and diagnostics arena have the experience to cope with these challenges. They usually have established departments or groups focusing on quality and regulatory topics, e.g. quality management and regulatory departments.

However, startups and young companies which initially focus on “proof of principle” and R&D sometimes neglect quality topics.

New Guide advisors can help to overcome this “neglect” and integrate quality and regulatory requirements from the very beginning of product development.