Risk Assessment and the Value of a Comprehensive Post-Market Surveillance Program

By Carol Young, Nerac Analyst

Risk Assessment plays an important role in getting products approved and placed on market. A robust Post-Market Surveillance Program will assist the manufacturer in continuously evaluating the safety and efficacy of these products.

There are several aspects to consider when developing a risk assessment plan. ISO 14971 has recently been modified to the New Approach Directive 93/42/EEC and medical device companies must revise the current risk assessment to meet the new requirements in order to remain compliant. These aspects include the following:

- Clinical data requirements
- Market surveillance plans and experience gained from the devices in a post-production environment
- On-going lifecycle process which is applicable to the Essential Requirements document
- The current ALARP (As Low As Reasonably Practicable) concept has an economic element and now risks must be reduced “as far as possible” without any economic consideration and manufacturers may no longer use the ALARP concept
- Section 6.2 of ISO 14971 requires the manufacturer to “use one or more of the following risk control options in the priority listed: (a) inherent safety by design; (b) protective measures in the medical device itself or the manufacturing process; (c) information for safety”, but leaves it up to the manufacturer as to how these options will be applied

It is now mandatory to include post market information in the Clinical Evaluation Report to justify the decision not to do additional post-market clinical follow-up on high risk products. Notified bodies are reviewing this information carefully at the time of CE marking and when auditing the manufacturer for recertification. With the current spotlight that is being placed on the reevaluation of notified bodies, manufacturers can expect additional evaluation of CERs especially during mandatory unannounced audits.
Common Pitfalls:

- Medical device manufacturers do not adequately review the risk assessment of the products on the market to determine the need for post-market clinical follow up.

- Maintain compliance with the following MEDDEV guidance documents as they are updated.
  1. MEDDEV 2.7/1: Clinical evaluation: Guide for Manufacturers and Notified Bodies
  2. MEDDEV 2.7/2: Guide for Competent Authorities in Making an Assessment of Clinical Investigation Notification
  3. MEDDEV 2.7/3: Clinical Investigations: Serious Adverse Event Reporting

- The notified bodies have a Checklist for audit of Notified Body’s review of Clinical Data/Clinical Evaluation: NBOG CL 2010-1 which provides guidance to auditors on what requirements must be met.

Post-market information has always played an important role in providing complaint data to the notified body, submitting MDRs to the FDA, and when the manufacturer is being audited. However, due to the recent product scandals (PIP, breast enhancement), the level of awareness has been elevated. Therefore, the manufacturers of medical devices must have post-market plans in place to review the on-going data in management review and SOPs that dictate relevant timeframes for review of products throughout the year. This data is then reviewed against the risk management plan to insure that there have been no new risks associated with these products.

In order to more closely monitor medical device products, the FDA has recently initiated a UDI (Unique Device Identifier) program to support public health initiatives and post-market surveillance activities. This UDI closely resembles a barcode, and identifies each manufacturer with a unique number, labeling and specific product information (e.g., whether the product is sterile and the sterilization method, expiry date, lot number) to better track the products that have been cleared for sale in the US market. This database will now allow for closer scrutiny of these products for compliance of safety and efficacy.

Medical Device manufacturers can expect that the EU, Canada and Australia will be initiating similar methods in order to monitor this information on a worldwide basis.

How can Nerac Help?

Medical device manufacturers continue to rely on Nerac to address compliance issues for medical devices on a regular basis. Nerac’s standardized, systematic approach to the evaluation and analysis of clinical data provides clients with the basis for initial and on-going compliance with regulatory requirements. While post market surveillance is not a new requirement, it is now clear that the notified bodies have placed an increased focus in this area and expect it to be an essential component of the overall clinical evaluation of marketed devices.

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About the Analyst

Carol Young

Carol Young has fifteen years of experience in the regulatory field and will be able to provide this unique perspective to the requests received from Nerac clients. This perspective incorporates experience with companies manufacturing both medical devices (Class III, Class IIb and Class IIa) and pharmaceuticals (oncology and combination products). She also has extensive knowledge in the areas of regulatory strategies and submissions relating to Domestic, EU and ROW (Rest of World) for new product launches and compliance issues concerning facility audits (for FDA, notified body, competent authorities and international regulatory authorities). She has managed Regulatory Affairs personnel and projects such as technical file/design dossier filings in the EU, Canada, Australia, Taiwan and Japan along with clinical trial applications in the EU and CTA submissions for INDs.

Academic Credentials

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