TATA ELXSI

POST MARKET SURVEILLANCE SERVICES

Periodic | Effective | Robust

Trending

As per the McKinsey report, the medical device industry spends USD 14-21 billion on maintaining day to day quality. This includes USD 1.5-3 billion per year on non-routine events, such as recalls, warning letters, major observations, consent decrees with additional USD 1-2 billion in lost sales of new and existing products.

Companies are preferring to proactively monitor their devices in the market to avoid such economic implications, maintain market reputation amidst increasing competition and deliver better patient safety.

Moreover, the renewed interest in monitoring devices post market launch can be attributed to continuously evolving region-specific regulatory requirements.

Opportunities & Challenges

Apart from adhering to regional regulatory requirements, the advantage of proactive post market surveillance (PMS) is to minimize clinical risk exposure to end-user and detect/ predict potential product failures in the field.

PMS gives an opportunity to the companies to improve upon the usability, performance and safety aspects of the device through establishing effective complaints management process and cross-pollinating the major/ key complaint trends.

Efficient identification of the need for preventive, corrective or field safety corrective action to ensure product sustenance is also of key concern to the manufacturers.

Benefits for consumers

- Proactive PMS by the manufacturers may potentially avoid threats associated with malfunctioning devices
- Established channels to log complaints with the medical device company and the authorities
- Due diligence of market complaints by manufacturers to improve on device performance, reliability, and safety

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Tata Elxsi PMS Assets

Standard SOP & customizable templates

Access to literature databases

Established QMS procedures, as per 21 CFR Part 822 and EU regulations

Post Market Surveillance workflow

Complaint Intake & Management

- Complaint confirmation
- Validity check
- Information sufficiency for investigation
- Use errors validation against IFU

Investigate

- Preliminary investigation
- Previously unreported issue(s) identification
- Failure mapping: Pre-stated or beyond trending limit
- New failure mode: Identification + root cause investigation
- Risk management file update
- Product recall/ CAPA, if warranted

Closure

- Document action, summary statement, closure type
- State ongoing CAPA, if applicable

Trend Analysis

- Analyze complaints
- Populate trend charts

To continually improve the safety and effectiveness of your devices for patients and users

Immediate Field Action

Vigilance Reporting

CAPA

Risk Management

Differentiators

- Efficient complaints handling processes with over 90% complaints closure rate
- Mature program management to accommodate customers' changing needs
- Industry experienced team of clinical, pre-market, post-market regulatory experts

Cases

Clearing complaints backlog of 15000+ recall products within a span of 7 months

- Performed gap assessment & statistical sample analysis to craft a custom remediation plan
- Developed sustainable processes and procedures, achieving a sustenance level of less than 1000 complaints per month
- Maintained WIP recall investigation above 90% against the target of 70%

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