novasyte health

S.M.A.R.T. RECALL PROGRAM

Recalls, software upgrades and field corrective actions happen.

Be prepared with Novasyte on your team.

Novasyte partners with med-tech companies, offering agility and flexibility with FDA recall, correction and removal support. Executing against your recall strategy, Novasyte offers closed-loop recall support for all levels of field actions – from non-reportable actions to the most urgent Class 1 recalls.

Novasyte tracks, manages and measures every activity in real-time back to a unique identifier. Our program also includes field-team deployment and the collection and warehousing of affected product, as needed.

Our proprietary, integrated data platform *tracks every consignee activity in real-time*, including but not limited to:

- **Notifications (written, phone and field)**
- **Digital signature capture**
- **Consignee acknowledgment**
- **Per-unit, serial number tracking**
- **Field-technician activities**
- **Product returns and RGAs**

Program success and associated costs are tracked and measured in our analytics platform. This offers clients real-time access to accurate consignee and per-unit data, as well as overall recall status. The platform is easily-accessible and features highly-organized data that is simple to understand, track and report on. This can save you valuable time and give you the confidence you need when it comes time to report to your leadership teams or the FDA.

Key Program Benefits

- **Quick Mobilization –** We understand and have a shared sense of urgency to move quickly following a decision to recall a product. As a result, we mobilize all aspects of a recall quickly - from notifications to the deployment of a field team.

- **Consignee Activity Tracking –** From notification to remediation, every action is closely tracked back to a unique identifier and reported in real-time on our analytics platform. This provides you the accurate data you need to quickly customize, export and share reports with the FDA.

- **Field and Phone Team Deployment –** As the outsourcing commercial services experts in the med-tech industry, we are able to quickly build, deploy, manage and measure all of the activities of our field teams in our integrated analytics platform.

- **On-site Remediation and Retrievals –** We have the ability to provide skilled technicians to manage on-site or remote remediation and retrieval.

Custom Plan Development

Each client has a unique set of needs and challenges when beginning to navigate these highly-complicated environments.

Novasyte develops custom plans for each client and has the experience and analytics platform to help you answer stakeholder questions on project progress in real-time.

Dedicated Account + Consultant Management

Account Management – Every client has a dedicated Account Manager and Account Executive to oversee and manage the recall process and support your ongoing needs. Your single point of contact is available 24/7 to support your needs in this rapidly changing environment.

Consultant Management – Novasyte is responsible for all recruitment, onboarding, hiring and training of the field-based teams. We ensure they are fully versed on the recall requirements to ensure accuracy and efficiency when in the field.

Retrieval + Warehousing

We deploy our dedicated call center and specialized med-tech field teams to efficiently retrieve the product from your customer's facilities – ensuring regulatory compliance and minimizing any operational disturbances. Our team is equipped to contain, remove, process, and store the affected product in our warehousing space.

Data-Driven Results

Novasyte's *S.M.A.R.T.* analytics platform is a proprietary platform that is uniquely designed to integrate and streamline your recall strategy.

Overall program success and associated costs are tracked and measured in our analytics and Tableau™ platforms. This offers clients real-time access to accurate consignee and per-unit data, as well as overall recall status. Customizable dashboards allows you to pull the data you need to report to the FDA or your leadership team on a weekly or monthly basis.

- **Interactive and Customizable Dashboards**
  Simple, clear and changeable data views allows you to filter the data to exactly what you need answering not only the questions you have now but also the questions you don't yet know you could be asking.

- **Data Types:**
  - KPI measurement
  - Affected product tracking and product return per unique serial number
  - Recall notification and delivery status
  - Consignee acknowledgment status
  - First pass yield tracking
  - Recall status reports
  - Field-based activities and spend by account, region, product, supervisor, task and unit

For more information:
Info@Novasyte.com

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