

# FDAWARE

The first cloud based platform to support companies regulated by the FDA in preventing 483s by leveraging a robust projection algorithm and implementing continuous process improvements.

Companies are searching for a focused and efficient approach to address their compliance challenges, reduce their exposure and mitigate compliance related risks while facing:

- ✓ **LIMITED Resources**
- ✓ **LIMITED Time**
- ✓ **LIMITED Budget**

- ✓ FDAWARE is an innovative Service for FDA's regulated industries, projecting compliance risks by leveraging current and historical 483s, recalls and warning letters.
- ✓ A company profile is used in conjunction with an advanced Projection Algorithm to assess specific sites and overall company compliance related risks, providing the site's team with potential compliance deficiencies sorted in the order of importance, to avoid costly consequences of incompliance.
- ✓ Trending reports are pushed to the compliance team, centralizing their focus on up-to-date FDA trends observed in their country, specific industry, region etc., creating a continuous improvement process.
- ✓ Fully integrated platform with FDA CFRs for Drugs, Biologics and Devices creating a fully aligned risk management platform with the FDA
- ✓ We have a team of professionals that are constantly monitoring new information about our industries; they are in contact with the FDA regularly and obtain the most up to date information about inspections, 483s, recalls, warning letters and more. We have over 55,000 Inspections in our DB since 2008, more than 15,000 483s; Recall Information since 2012, Monthly update of ALL the above information is being obtained. We also have Information about more than 2,000 Inspectors and their statistics (current and historical)
- ✓ Our software solution includes robust reporting Investigators & Inspections, 483s, Recall Information, and more, we have a dashboard to keep you up-to-date with your company compliance risks and mitigation progress, our project management module allows our customer to link any mitigation effort to the source generates the correction action; our robust DB provides endless opportunities to search for relevant information and save query; our comprehensive audit module provides hundreds of questions by industry type that are connected to historical observations



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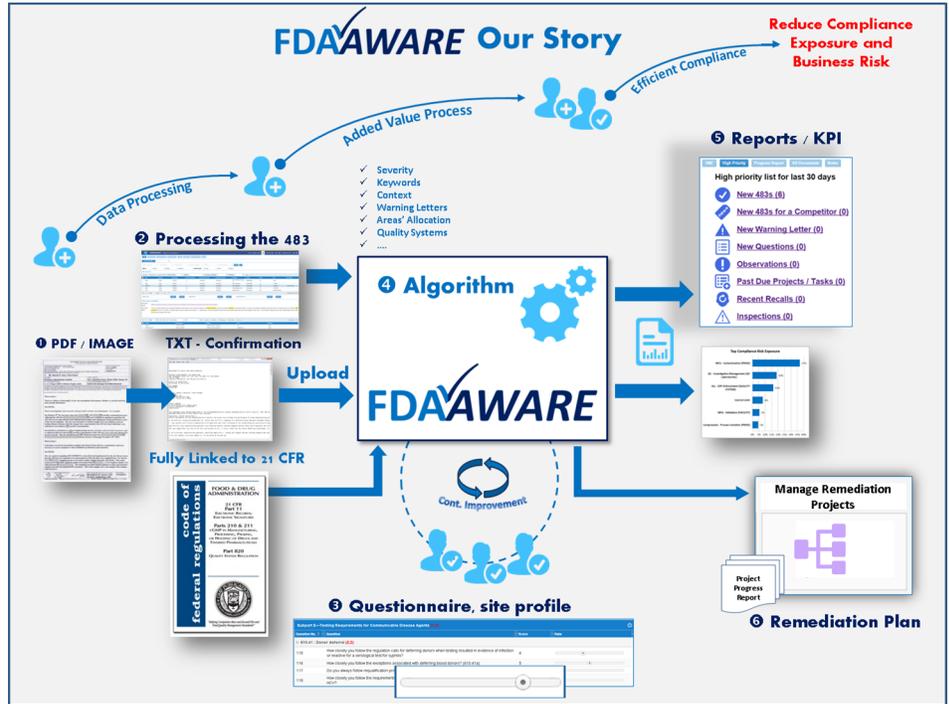
The ONLY cloud based risk management platform fully integrated with FDA FOIA gathering compliance intelligence to reduce likelihood/severity of 483

Our partners work with their clients to create their compliance profile using a comprehensive proprietary auditing questionnaire and in conjunction with an advanced Projection Algorithm, assessing for each specific sites and overall company their compliance related risks; We then provide the site's team with potential compliance deficiencies prioritized by the order of importance, to avoid costly consequences of incompliance.

At the end of the process FDAWARE goals are:

- ✓ Provides "Real" Time Access To Company-specific Compliance Risk Information
- ✓ Empowers Company By Providing Insight Into Potential FDA Inspection Agenda
- ✓ Enables Effective Resource Allocation
- ✓ Supports Management Decision Making Process
- ✓ Improves Company's FDA Inspection Readiness
- ✓ Reduces Risk Exposure
- ✓ Facilitates Effective Project Identification And Prioritization
- ✓ Reduces Operations Cost

- ✓ FDAWARE enables companies to easily identify their potential compliance deficiencies, by utilizing a robust algorithm, data mining of historical 483s, industry trends, regional influences and segmentation, the platform generates compliance risk areas applicable to a specific user profile.
- ✓ Once risks are identified by the FDAWARE platform, a what-if analysis can be conducted to ensure resources are allocated to the areas with the greatest impact on company's compliance. Use FDAWARE project management module to define the remediation projects and create a continuous improvement program.
- ✓ All it takes is ONE-TWO days; FDAWARE experts will assist the customer to build its unique profile in our web based solution. The profile consists of data including industry, region, weaknesses, strengths, historical data and more. By the end of the process, the platform will be customized according to company specific profile ensuring targeted and accurate results.



For additional information contact us at: [www.fdaaware.com](http://www.fdaaware.com)

