Regulatory Intelligence on Biologics Recalls – Immunoglobulins and Vaccines are Involved in More Recalls than Other Drug Classes

Description:  GBI Research’s report, “Regulatory Intelligence on Biologics Recalls – Immunoglobulins and Vaccines are Involved in More Recalls than Other Drug Classes”, provides in-depth analysis of biologics recalls issued or reported with the US Food and Drug Administration (FDA) and its constituent agencies. The report analyzes biologics recalls on the basis of the reason for recall, therapy area, drug class, dosage forms and the recalling company, on a year-to-year basis from 2007–2010. The report is built on data and information sourced from the FDA database of biologics recalls and in-house analysis by GBI Research’s team of industry experts.

GBI Research found that biologics recalls have significantly increased from 2004–2010 due to a number of underlying causes, which are explained in detail in the report. Of biologics recalls made between these years, recalls for vaccines and immunoglobulins were higher than other drug classes. The reasons for recalls varied from serious adverse events, labeling errors and quality defects, to manufacturing defects. Of the biologics recalled since 2004, the highest number of recalls occurred in 2010, followed by 2008. In 2010, the infectious diseases and immunodeficiency disorders therapy areas had the most biologics recalls.

Scope
- Data and numerical figures on the number of biologics recalls issued according to the year of recall and recalling firm, from 2007–2010.
- Analysis of leading therapeutic areas and dosage forms for major biologics recalls.
- Case studies of companies that have recalled biologic products and re-released products with manufacturing changes or labeling changes.

Reasons to buy
- Understand the pattern of biologics recalls, along with their underlying causes, in order to enable you to undertake strategies to protect products from encountering safety issues.
- Analyze the key reasons for recalls, along with the therapy areas and class of recalled biologics most vulnerable, so as to strengthen the areas which may lead to quality defects in your company’s products.
- Reinforce quality and manufacturing strategies in order to be complaint with the current regulatory norms.
- Develop strategic initiatives through understanding of the key focus areas of biologics recalls.

Contents:
1 Table of Contents
1.1 List of Tables
1.2 List of Figures
2 Introduction
2.1 Drugs and Biologics Inspections and Warning Letters
2.2 Public Health Service Act and Biologics
2.3 Drug Recall Process
2.4 Drug Recalls Reported by CDER
2.5 Drug Recalls Reported by CBER
2.6 GBI Research Report Guidance
3 Regulatory Intelligence on Biologics Recalls: Overview
3.1 Overview of Biologics
3.2 Overview of Biologics Manufacturing Process
3.3 Biologics Recalls
3.4 Reasons for Recalls
3.5 Risk Management for Drugs and Biologics
3.5.1 Labeling Revisions on ESAs Following FDA Recommendation and CMS Changes to Reimbursement
3.5.2 Updated Labeling of Tysabri to Warn Against Increased Risk of Progressive Multifocal Leukoencephalopathy (PML)

3.6 Regulatory Responsibilities and Procedures Involving Recalls
3.6.1 Reasons for Manufacturers to Initiate Recalls
3.6.2 FDA Responsibilities and Procedures Outline
3.6.3 Responsibilities of the Agencies Involved

3.7 Case Study 1 - Octagam 5% Returned to Market after Resolution of Manufacturing Issues by Octapharma
3.7.1 Octagam 5% Recalled from Markets Due to Increase of Thromboembolic Events (TEEs)
3.7.2 Changes to the Manufacturing Process
3.7.3 Favorable Opinion of Regulatory Authorities and Approval of the Product

3.8 Case Study 2 - Heparin Crisis a Reflection of FDA Failure
3.8.1 Heparin Contamination Forced Several Companies to Recall Products
3.8.2 Source of Contamination was in China
3.8.3 Regulatory Failure Led to Contaminated Heparin Distribution

3.9 Case Study 3 - Shortened Expiration Period for 2009 H1N1 Vaccine in Pre-filled Syringes by Sanofi Pasteur
3.9.1 Five Lots with Lower than Pre-Specified Potency Levels Recalled from the Market
3.9.2 Change of Expiration Date for the Remaining Lots as a Protective Measure

4 Regulatory Intelligence on Biologics Recalls – Trends Analysis
4.1 Analysis of Biologics Recalls 2004–2010
4.1.1 Reasons for Biologics Recalls
4.1.2 Biologics Recalls by Therapy Area
4.1.3 Biologics Recalls by Drug Class
4.1.4 Biologics Recalls by Different Dosage Forms
4.1.5 Biologics Recalls by Companies
4.2 Analysis of Biologics Recalls 2007–2010
4.2.1 Reasons for Biologics Recalls
4.2.2 Biologics Recalls by Therapy Area
4.2.3 Biologics Recalls by Drug Class
4.2.4 Biologics Recalls by Dosage Form
4.2.5 Biologics Recalls by Companies
4.3 Analysis of Biologics Recalls – 2007
4.3.1 Reasons for Biologics Recalls, 2007
4.3.2 Biologics Recalls by Therapy Area, 2007
4.3.3 Biologics Recalls by Drug Class, 2007
4.3.4 Biologics Recalls by Dosage Form, 2007
4.3.5 Biologics Recalls by Companies, 2007
4.4 Analysis of Biologics Recalls – 2008
4.4.1 Reasons for Biologics Recalls, 2008
4.4.2 Biologics Recalls by Therapy Area, 2008
4.4.3 Biologics Recalls by Drug Class, 2008
4.4.4 Biologics Recalls by Dosage Form, 2008
4.4.5 Biologics Recalls by Companies, 2008
4.5 Analysis of Biologics Recalls – 2009
4.5.1 Reasons for Biologics Recalls, 2009
4.5.2 Biologics Recalls by Therapy Area, 2009
4.5.3 Biologics Recalls by Drug Class, 2009
4.5.4 Biologics Recalls by Dosage Form, 2009
4.5.5 Biologics Recalls by Companies, 2009
4.6 Analysis of Biologics Recalls – 2010
4.6.1 Reasons for Biologics Recalls, 2010
4.6.2 Biologics Recalls by Therapy Area, 2010
4.6.3 Biologics Recalls by Drug Class, 2010
4.6.4 Biologics Recalls by Dosage Form, 2010
4.6.5 Biologics Recalls by Companies, 2010

5 Regulatory Intelligence on Drug Recalls - Appendix
5.1 Market Definitions
5.2 Abbreviations
5.3 Research Methodology
5.3.1 Coverage
5.3.2 Regulatory Intelligence on Biologics Recalls – Overview
5.3.3 Regulatory Intelligence on Biologics Recalls – Trend Analysis
5.4 Contact Us
5.5 Disclaimer
5.6 Sources

1.1 List of Tables
Table 1: Regulatory Intelligence on Biologics Recalls, Total Number of Recalls by All Agencies, 2007–2010
Table 2: Regulatory Intelligence on Biologics Recalls, Drug Recalls by CDER, 2007, 2008 and 2010
Table 3: Regulatory Intelligence on Biologics Recalls, Number of Drug Product Recalls by CDER by Class, 2007, 2008 and 2010
Table 4: Regulatory Intelligence on Biologics Recalls, Drug Recalls by CBER, 2007, 2008 and 2010
Table 5: Regulatory Intelligence on Biologics Recalls, Number of Biological Product Recalls by CBER by Class, 2007, 2008 and 2010
Table 6: Regulatory Intelligence on Biologics Recalls, Product Recalls by CDER, CBER and Other Agencies, 2007, 2008 and 2010
Table 7: Regulatory Intelligence on Biologics Recalls, Total Number of Biologics Recalls, 2004
Table 8: Regulatory Intelligence on Biologics Recalls, Total Number of Biologics Recalls, 2005
Table 9: Regulatory Intelligence on Biologics Recalls, Total Number of Biologics Recalls, 2006
Table 10: Regulatory Intelligence on Biologics Recalls, Total Number of Biologics Recalls, 2007
Table 11: Regulatory Intelligence on Biologics Recalls, Total Number of Biologics Recalls, 2008
Table 12: Regulatory Intelligence on Biologics Recalls, Total Number of Biologics Recalls, 2009
Table 13: Regulatory Intelligence on Biologics Recalls, Total Number of Biologics Recalls, 2010
Table 14: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall, 2004–2010
Table 15: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall, By Year, 2004–2010
Table 16: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area, 2004–2010
Table 17: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area, By Year, 2004–2010
Table 18: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Drug Class, 2004–2010
Table 19: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Drug Class, By Year, 2004–2010
Table 20: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Dosage Form, 2004–2010
Table 21: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Dosage Form, By Year, 2004–2010
Table 22: Regulatory Intelligence on Biologics Recalls, Recalls by Companies, 2004–2010
Table 23: Regulatory Intelligence on Biologics Recalls, Recalls by Companies, By Year, 2004–2010
Table 24: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area, 2004–2010
Table 25: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area, 2007–2010
Table 26: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Drug Class, 2004–2010
Table 27: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Drug Class, By Year, 2004–2010
Table 28: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Dosage Form, 2004–2010
Table 29: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Dosage Form, By Year, 2004–2010
Table 30: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Companies, 2004–2010
Table 31: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Companies, By Year, 2004–2010
Table 32: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall, 2007–2010
Table 33: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall, By Year, 2007–2010
Table 34: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area, 2007–2010
Table 35: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area, By Year, 2007–2010
Table 36: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Drug Class, 2007–2010
Table 37: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Drug Class, By Year, 2007–2010
Table 38: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Dosage Form, 2007–2010
Table 39: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Dosage Form, By Year, 2007–2010
Table 40: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Companies, 2007–2010
Table 41: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Companies, By Year, 2007–2010
Table 42: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall, 2008–2010
Table 43: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall, By Year, 2008–2010
Table 44: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area, 2008–2010
Table 45: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area, By Year, 2008–2010

1.2 List of Figures
Figure 1: Regulatory Intelligence on Biologics Recalls, Total Number of Recalls by All Agencies, 2007–2010
Figure 2: Regulatory Intelligence on Biologics Recalls, Drug Recalls by CDER, 2007, 2008 and 2010
Figure 3: Regulatory Intelligence on Biologics Recalls, Number of Drug Product Recalls by CDER by Class, 2007, 2008 and 2010
Figure 4: Regulatory Intelligence on Biologics Recalls, Drug Recalls by CBER, 2007, 2008 and 2010
Figure 5: Regulatory Intelligence on Biologics Recalls, Number of Biological Product Recalls by CBER by Class, 2007, 2008 and 2010
2007, 2008 and 2010
Figure 6: Regulatory Intelligence on Biologics Recalls, Product Recalls by CDER, CBER and Other Agencies, 2007, 2008 and 2010
Figure 7: Regulatory Intelligence on Biologics Recalls, Biologics Manufacturing, Biologics Classification, 2009
Figure 8: Regulatory Intelligence on Biologics Recalls, Biologics Manufacturing, Biologics Manufacturing Steps, 2009
Figure 9: Regulatory Intelligence on Biologics Recalls, Reasons for Manufacturing Initiating Recalls
Figure 10: Regulatory Intelligence on Biologics Recalls, FDA Responsibilities
Figure 11: Regulatory Intelligence on Biologics Recalls, Total Number of Biologics Recalls, 2004–2010
Figure 12: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall, 2004–2010
Figure 13: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area, 2004–2010
Figure 14: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Drug Class, 2004–2010
Figure 15: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Dosage Form, 2004–2010
Figure 16: Regulatory Intelligence on Biologics Recalls, Recalls by Companies, 2004–2010
Figure 17: Regulatory Intelligence on Biologics Recalls, Recalls by Companies, By Year, 2004–2010
Figure 18: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall, 2007–2010
Figure 19: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area, 2007–2010
Figure 20: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Drug Class, 2007–2010
Figure 21: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Dosage Form, 2007–2010
Figure 22: Regulatory Intelligence on Biologics Recalls, Recalls by Companies, 2007–2010
Figure 23: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall (%), 2007
Figure 24: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area (%), 2007
Figure 25: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Drug Class (%), 2007
Figure 26: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Dosage Form (%), 2007
Figure 27: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Companies (%), 2007
Figure 28: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall (%), 2008
Figure 29: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area (%), 2008
Figure 30: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Drug Class (%), 2008
Figure 31: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Dosage Form (%), 2008
Figure 32: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Companies (%), 2008
Figure 33: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall (%), 2009
Figure 34: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area (%), 2009
Figure 35: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Companies (%), 2009
Figure 36: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Reason for Recall (%), 2010
Figure 37: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Therapy Area (%), 2010
Figure 38: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Companies (%), 2010
Figure 39: Regulatory Intelligence on Biologics Recalls, Biologics Recalls by Companies (%), 2010

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