

## **Consent Decree: The History and Impact**

Many Years Ago Schering Plough underwent the first Consent Decree.

Since, then many years have elapsed and the term Consent Decree was foreign to many employees and employers and to Industry overall. Over the last seven years there has been a huge onset of Regulatory Enforcement and Consent Decree Action by the Agency.

As we explore top Regulatory Enforcement trends in the area of Consent Decree, we see that key areas of focus and Regulatory Enforcement are: Computer Systems Validation (focusing on 21CFR Part 11, Electronic Records and Signatures (ERES), Equipment Qualification, Change Control Systems, Proper Laboratory Investigations, Corrective Action/Preventative Actions (CAPA), Root Cause Analysis (RCA), etc.

### **What is a Consent Decree?**

FDA uses Consent Decree to change overall corporate culture in compliance matters by pulling the company out of a pattern of long-standing cGMP problems and raising it to current standards.

- Consent Decree is a legal agreement between the company and the government (in this case FDA/The Agency)
- It is a negotiated agreement detailing the voluntary actions pledged by the affected company to remedy non-conformances, including systems improvements and to avoid FDA litigation.
- A Consent Decree commits the company to performing corrective actions in timely manner, as verified by a third party.
- Consent Decrees are usually imposed as a result of continual non-conformance in a company's quality management systems.
- Continual non-conformance is defined as repeated Form 483 observations typically transmitted to a company over the course of several audits and inspections.

- A repeated “Unsatisfactory” or “No Response” from a company to FDA Warning Letters also may be reason for FDA action.
- The consent decree ensures that the company will meet the required GMP guidelines.
- It allows the company to remain in business and ensure that all consumers continue to receive medications of reasonable QUALITY.
- A Consent Decree may be viewed as the equivalent to a Court Order under which the manufacturing and distribution of products can resume, with conditions closely monitored by the FDA.
- It is a voluntary agreement signed by the firm’s top official, the US Attorney and the US District Court.

### **It is filed with the Court and Submitted to the FDA**

- Before a consent decree is issued FDA must show evidence that both parties have made clear efforts to resolve noncompliant solutions.
- The company and the FDA review the warning letters, 483s and other communications. Thus, a consent decree should not be a surprise to the company.

Once the consent decree is issued, the company is required to cancel or stop production of nonessential and multi-source products. The company may be forced to assign testing and release functions and responsibilities (such as certification of investigation, approval of validation protocols and reports, and annual audits, etc.) to a third party

The third party plays a major role in the consent decree and post-consent decree periods. In addition to paying a fine, the company may be forced to delay new product introductions and pay additional fines (\$15,000/day per item) for not completing the corrective actions on an agreed upon timeline.

Generally speaking, a consent decree is considered permanent and it takes several years for a company to demonstrate they are in full compliance. Over the last seven to ten years there has been a significant increase in the number of Consent Decrees in the healthcare industries (Pharmaceutical, Medical Device, Biologics, etc.):

- There has been a significant increase in Global Regulatory/Compliance Implications.
- Many foreign regulatory Issues in India and China and focusing on laboratory data integrity and overall computer systems validation.
- There are approximately sixteen (16) major pharma consent decrees dating from 1989-2010.
- Many consent decrees have still not been vacated/cleared thus leaving “Regulatory Handcuffs” on the firm in question.

### **Financial Consent Decree Impact:**

- ~\$8.5 Billion: Costs related to Regulatory Infractions by 9 leading pharmaceutical companies over the past 7 years.
- ~625 products recalled since 2011.
- Hundreds of millions of dollars spent on consultants and 3<sup>rd</sup> party auditors.
- Companies lose huge valuation in their stocks and immediately become takeover targets for other healthcare firms at a significant reduced overall cost.
- Many firms have been acquired in the last decade due to Consent Decree...In effect many previously successful firms are bought overnight (after Consent Decree Issuance) for little money.
- More or less the industry and regulatory landscape is significantly changing both domestically and internationally due to Consent Decree.

### **What Are the Top Consent Decree Regulatory Challenges and Trends?**

- Quality Units
- Data Integrity
- Computer Systems Validation
- Manufacturing Controls
- Quality Control
- Aseptic Processes (Injectables, IV's, Vaccines, etc.)
- Environmental Monitoring/Conditions
- Stability
- CAPAs (Corrective Action Preventative Action)
- Inadequate oversight of vendors throughout the supply chain
- Inadequate Design Control
- Product Design (Medical Device)
- Manufacturing Process control (Medical Device)
- International Regulatory Issues with the Onset of many Relatively New Countries/Firms expanded into the Worldwide Healthcare Network

*About the author: Gaurav Walia has over 19+ years of Pharmaceutical experience, and has worked as a Pharmaceutical Consultant in various disciplines from Quality Systems, Consent Decree, and Computer Systems Validation. He has experience from his beginnings as an Analytical R&D Chemist to Asst. Director of Pharmaceutical Operations to Director of Quality Assurance and Compliance. Mr. Walia has managed various technical, quality and compliance groups, such as, Pharmaceutical Research and Development, Laboratory Information Management Systems (LIMS), Quality Control (QC), Materials Import and Export, Safety, Validation, Quality Assurance and Compliance, Regulatory Compliance, and many more. His Mr. Walia's diverse multi-disciplined background has yielded years of success towards internal audit excellence, successful remediation projects, as well as over 100+ Regulatory Audits both domestic (FDA) and international (sFDA/Chinese FDA, EMEA, IMB, etc.) which in total were successful inspectional audits.*

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