Case Study

21 CFR 212 - Compliance Training
Cardinal Health, Inc. (Healthcare)
About the Customer

Cardinal Health is a Fortune 500 company that is constantly working on improving the cost-effectiveness of healthcare. As the business behind healthcare, Cardinal Health helps pharmacies, hospitals and ambulatory care sites focus on patient care while reducing costs, improving efficiency and quality, and increasing profitability. Cardinal Health employs more than 30,000 people worldwide.

Cardinal Health also operates the world’s largest network of nuclear pharmacies and is expanding its Positron Emission Tomography (PET) agent manufacturing capabilities to support new drug development and the future of personalized medicine. In addition, about 200 hospitals across the US outsource the management of their inpatient pharmacy to Cardinal Health because of its proven expertise and track record of improving efficiency and safety within inpatient pharmacies.

The Customer’s Needs

In 2006, Cardinal Health acquired five PET radiopharmaceutical production facilities and managed a sixth site to create a more efficient approach to the manufacturing and distribution of PET radiopharmaceuticals. This investment enabled a more streamlined approach to deliver the highest level of quality and service to the PET imaging centers supported by Cardinal Health’s nationwide network. Cardinal Health’s strategic goals further included:

- **Achieve faster Food and Drug Administration (FDA) approvals:** Increased focus on reliability and accuracy of data on test results and adequacy of manufacturing processes and controls.

- **Attain 21 CFR 212 Compliance:** Starting with the year 2009, Cardinal Health had two years to achieve the 21 CFR Part 212 compliance.

- **Increase Compliance Adherence:** Achieve complete compliance adherence around submissions to government agencies and maximum accuracy in internal records management.
The InfoPro Solution:

InfoPro developed a series of interactive and self-paced Web-based Trainings (WBTs) that offer conceptual knowledge with a high-level mastery. With the knowledge gained through the WBTs, the learners are capable of handling diverse situations involving legal predicaments related to documentation of drug patents and production. The trainings covered the following areas:

- Evolution of drug regulation in the United States of America,
- Adulteration and misbranding as defined by the FDA agency,
- Good Manufacturing Practices (GMPs) used for PET drugs and new products, and
- Data Integrity laws and various Standards for Business Conduct at Cardinal Health and the GMPs for new drugs followed at Cardinal Health.

The Instructional Strategy:

Content was arranged in easy-to-understand capsules of knowledge. A detailed audience analysis identified the diverse audience demographics to include in-house and on-site employees such as Supervisors, Technicians, Quality Assurance Staff, etc. The trainings catered to visual, auditory and kinesthetic learning styles. Additionally, the strategy included Bloom’s Taxonomy, Gagne’s Nine Events and Adult Learning Principles to promote quality training.

To promote comprehension of the subject matter and to make the content engaging and interactive for the learners, the WBT included the following media and instructional strategies:

- Tab Type Activity
- Case Study
- Clickable Buttons
- Walking Beanie Animation
- Scenario-based Knowledge Checks

For Legal and Historic content, which is quite dry and dreary for learners to comprehend, the WBT offered following instructional approach:

- Pop-up functionality
- Roll-over image zoom
- Winding Path
- Timeline
- Animated Flash Cards
- Roll-over Buttons
Learning Outcomes

InfoPro has over two decades of experience in developing content solutions. We have worked extensively in helping customers keep pace with changing technology landscapes. While we deliver significant value through our innovative use of technologies, our process excellence doubles the value delivered to our customers. Major business benefits delivered to Cardinal Health included:

- Improved accuracy in records management for:
  - Batch records
  - Laboratory records
  - Test results (stability tests, sterility tests, etc.)
  - Other records (e.g., Narcotic Control Records, Corrective and Preventive Actions, complaints, and equipment.)

- Improved accuracy in statements (verbal, written, electronic, etc.) made to government inspectors and agencies including:
  - Abbreviated New Drug Application or New Drug Application submissions
  - Drug Master File submissions
  - Responses to FDA 483 observations
  - Documents provided or statements made during agency inspections

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- Data integrity compliance training improved accuracy in records management and government submissions.
InfoPro Learning – The Right Choice

InfoPro Learning helps organizations rapidly transform talent by focusing on Learning for Performance. A global, award-winning learning and training solutions company for almost 20 years, InfoPro provides performance improvement strategies, blended learning solutions and managed training programs. At InfoPro, performance innovation, cutting-edge technology and a talented team are combined to deliver successful workforce solutions and business outcomes. InfoPro Learning is obsessed with helping customers build training capacity, advance their practices and respond effectively to changing learner needs.

For more information about InfoPro Learning, Inc., visit: www.infoprolearning.com, call (609) 606-9020 or email us at info@infoprolearning.com

Awards & Recognitions
- 2014 & 2013 TrainingIndustry.com Top 20 Content Development Companies List
- 2014 & 2013 TrainingIndustry.com Top 20 Training Outsourcing Companies List
- 2013 CLO Learning In Practice Silver Award
- 2012 Brandon Hall Gold Excellence Award for Content Development
- 2012 Brandon Hall Gold Excellence Award for Best Advance in Social Learning Technology