



Wyeth



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Press Release – 24th June 2007 TDS Secure FDA Qualification in Wyeth Medica Ireland

TDS' CoreAccess Solution Secures FDA Compliance in Wyeth Medica

TDS' **CoreAccess** solution, which has been implemented in Wyeth Medica Ireland for over 5 years, has recently secured FDA qualification in Wyeth's Newbridge plant.

Wyeth Medica Ireland (WMI) was established in Newbridge, Co. Kildare in 1992. The plant employs over 1400 people in a facility of over 1,000,000 sq ft. WMI manufacture over 140 products to treat and help prevent some of the world's most serious health problems.

The Food and Drug Administration (FDA) have adopted a strategic initiative to modernise the regulation of pharmaceutical manufacturing and product quality. The initiative aims at ensuring that regulatory review, compliance and inspection policies are based on state-of-the-art pharmaceutical science and do not impede rapid adoption of new technological advances by the pharmaceutical industry. It also enhances safety and quality of drug manufacturing while increasing efficiencies.

CoreAccess qualification with the FDA Rules, govern the following:

- Submitting electronic records and using electronic signatures. 21 CFR Part 11 also covers how the records shall be produced to be deemed trustworthy and how electronic signatures shall be applied to make the FDA consider them equivalent to full handwritten signatures.
- Comprehensive Audit Trail and Analysis. **CoreAccess** automatically maintains a secure, date and time-stamped audit trail of all changes made to any electronic record. Users making changes are fully audit trailed detailing who, what, where and when.
- The FDA approved **CoreAccess** system provides comprehensive and enhanced features in the area of Password Control, examples being; password aging, enforcing password change after a defined period, automatic lock-out after a number of invalid access attempts, enforced password complexity to avoid simple passwords, minimum password length, limit number of user sessions, inactivity timeout and comprehensive user account profiling.

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