

## PHARMACY & FORMULATION

*Pristima® XD Core is a fully integrated, end-to-end enterprise solution for tracking and managing veterinary facilities and research subjects throughout the preclinical research process.*

*For over 40 years, global pharma companies and CROs have relied on Xybion to drive data collection workflows while ensuring quality, efficiency, and compliance.*

*Need flexible deployment? Xybion offers on-premise or hosted solutions.*

*Are You SEND Ready? Pristima's Savante™ module provides the most automated solution to produce SEND datasets.*

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### Comprehensive Laboratory Materials Management

Pristima® XD Core's **Pharmacy and Formulations module** is designed to record and maintain data relating to test materials receive, used and disposed of by the laboratory's pharmacy unit. Access to this module is controlled by authorization roles that include privileges for moving, distributing or using materials in a formulation.

Online formulation is strictly enforced through step-by-step instructions and weight confirmation. The Pharmacy and Formulations module is tightly integrated with the Pristima® study protocol and data but may be used as a stand-alone module for laboratories that have not adopted the full Pristima® XD Core.

### Data Management and Reporting Features

- Highly customizable to meet site-specific sops
- Materials master records
- Materials inventory management & tracking
- Materials archival and disposal records
- User-defined template formulation instructions
- Wide variety of formulation types
- Study-driven formulations
- Non-study formulations
- Online execution of the formulation
- Built-in supervisory reviews & approvals
- Built-in bar code labeling & scanner interfaces
- Built-in bi-directional interface for balances
- Fully integrated component of the Pristima® XD Core
- 21 CFR Part 11 electronic signatures and audit trail compliant

### Software Validation

Preclinical research clients using Pristima® XD Core must comply with GLP guidelines which require validation of all laboratory information management systems. Our experts deliver timely services in compliance with current guidelines and best practices to ensure a successful, timely, and cost-effective validation project.

- Project management
- Requirements documentation
- IQ/OQ/PQ test protocols
- Custom user guides
- Validation trace matrices
- Validation report