



Digitally Enabling Life Sciences and Health Systems Companies to Bring New Products to Market Faster

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Chairman & CEO

Xybion Digital (TSXV: XYBN)



A New Digital World Realities For Life Sciences Companies

COVID-19 has put a sharp focus on digital transformation and the need to have the critical medicines and vaccines approved rapidly for treating patients

-The Need-

- Quickly translate ideas into innovations. Rapidly produce the designed molecules to start testing
- Rapidly ensure the safety of new drugs and vaccines
- Digitize and bring all processes together from drug discovery, research, preclinical trials, to clinical trials, while ensuring the full chain of custody of all samples, pharmaceuticals, supplies, and data to ensure full compliance
- Embed predictive compliance and quality and risk management in the process for full FDA Compliance
- Automate documentation of everything with full audit trails
- Assure health and safety of the employees.
- Utilize digital processes and cloud architectures to allow seamless work on-site and from remote locations

We Provide end-to-end, functional rich software for entire lab operations on a Low-Code SaaS Platform.

-Low capital investment...pay as you use model-						-Sample Clients						
	RESEARCH	DEVELOPMENT	MANUFACTURING & SUPPLY CHAIN	Quality and Compliance	HR, SAFETY, CORPORATE							
Drug Research, Development, and Testing												
			Clinical Testing			Regulatory						
	Drug Research, Development, and Testing											
	All-in-One Digital Lab Management System – LIMS, ELN, QMS, and DMS											
	Patented Predictive Compliance, Quality Management System, Risk Management											
	Total Employee Health and Safety Platform											
	Enterprise Content Management System with Embedded Regulatory Compliance											

160+ Clients
100% of Top 20

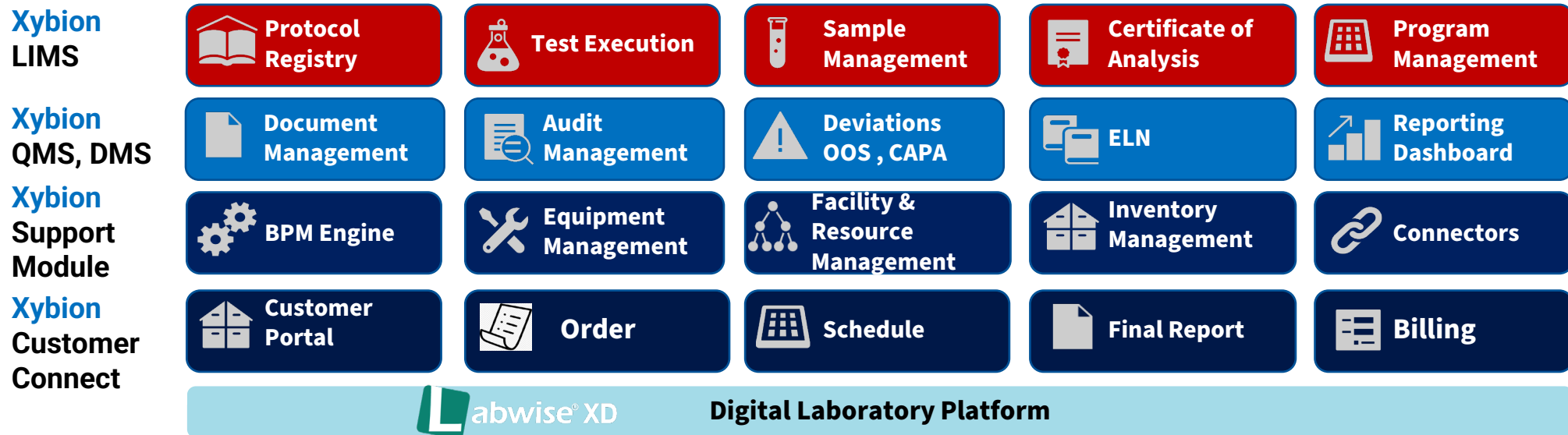
In 29 Countries

Offices in USA, Canada, Europe and India

Headquarters: Princeton, NJ

Early-stage life sciences organizations only need Xybion + Human Resource Management + Finance system to be fully operational and regulatory compliant.

-End-to-End digital process for Life sciences R&D and regulated labs.

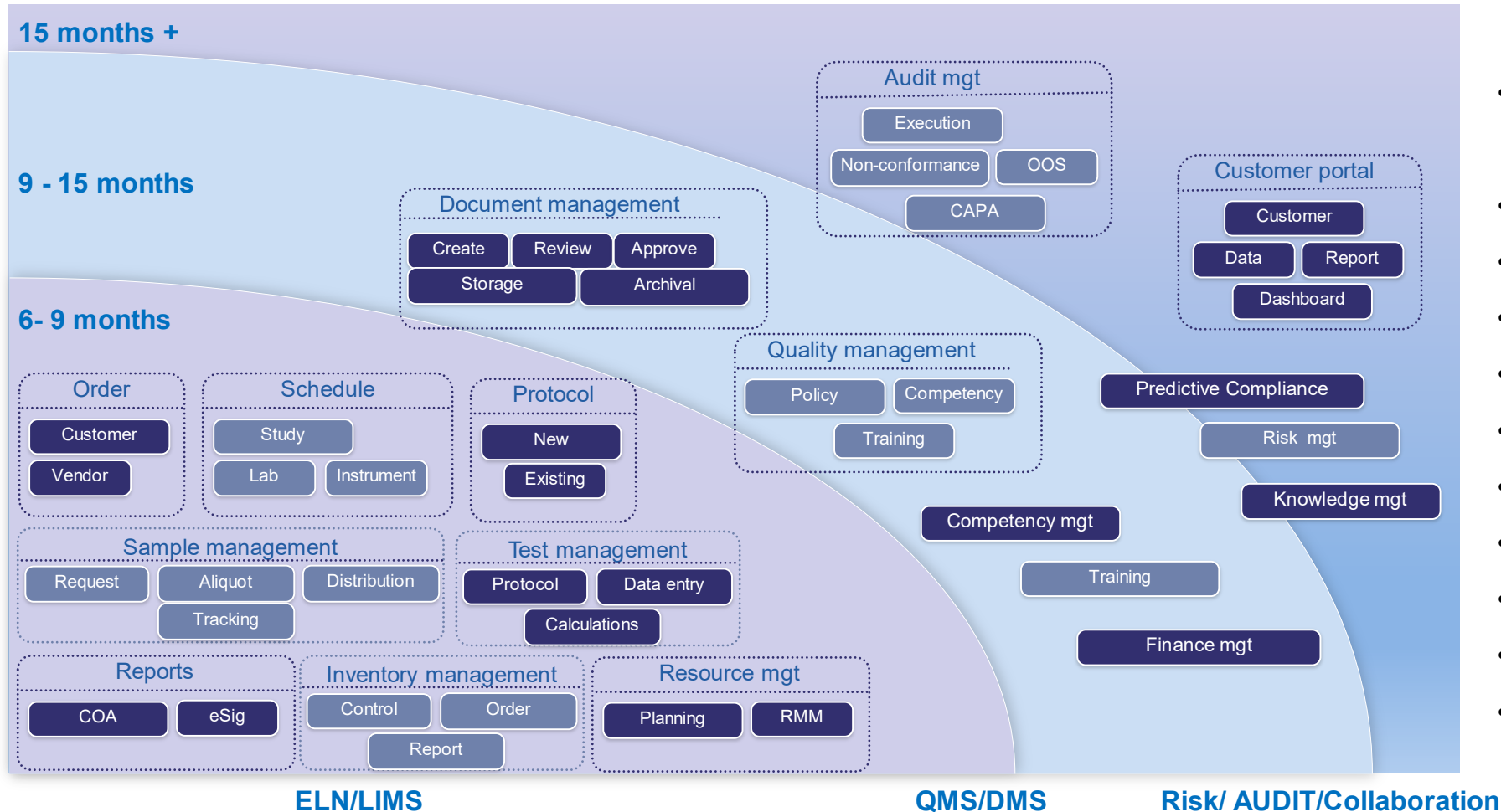


Segment specific bundled solutions for Gene Therapy, Diagnostic labs, Generic & Specialty Pharma. Companies, Enterprise Content and Protocol management, SOP and Competency Management, Facility, Instruments, Materials Compliance and Governance.

Digital Lab Execution system, a low CAPEX solution

Complete lab automation system using a simple platform-based architecture and a roadmap

- Unified solution, not traditional integration based
- Modular approach with an end goal and roadmap
- No IT infrastructure or investment needed



- End-to-end lab management on a single platform
- ELN
- Virus production & inventory mgt
- Protocol management
- QC
- Document management
- Project management
- Audit management
- Planning and cost mgt
- Invoicing
- Lab predictions, Training mgt

Client Successes

Case examples

World's Largest Pharmaceutical Company

Xybion's SaaS platform was rapidly configured to bring the internal scientific processes and their data into a single cloud to manage around 30,000 research protocols with role-based permissions and full security control for over 100,000 users worldwide.

Early Stage Biotechnology Company

This client utilizes Labwise XD for gene and immune therapies, sample management, all-in-one LIMS, quality management system, electronic lab notebook, and biopharma research-specific modules from Xybion. They can now manage their entire biotech business on a single cloud platform. The client is now fully operating with Xybion's Labwise XD covering all laboratory needs and a third party HRM and corporate finance system.



Northwell Health through rapid growth and multiple acquisitions has 23 hospitals with over 72,000 employees. Xybion's Evidence health and Safety module is used by Northwell Health of New York from the beginning of the pandemic to manage the safety of its entire workforce.



After selecting Xybion's Pristima XD for their preclinical R&D dept. and seeing our fully unified Quality and compliance software in the cloud, Boehringer Ingelheim Awarded us two more contract to replace its current QMS software vendor, a large company, by Xybion's fully unified CQRM XD module.

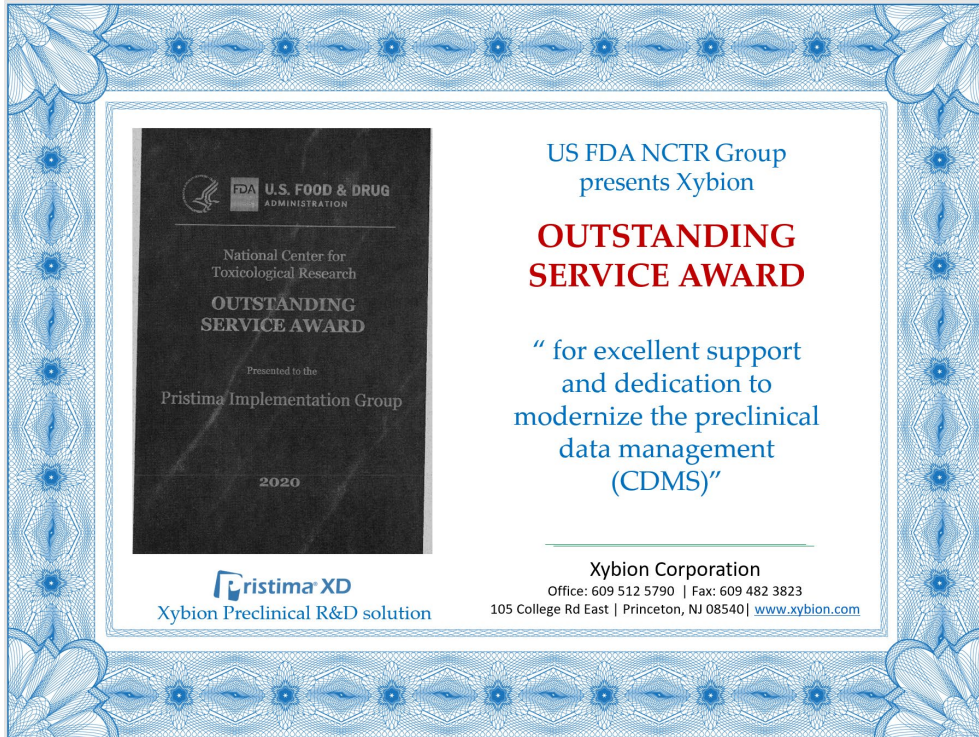
Why All Top 20 Biopharmaceutical Companies Choose Xybion

We Drive Growth in Regulated Environments.



Xybion Software and Services are Award Winning

Awarded By:  **U.S. FOOD & DRUG ADMINISTRATION**



Trusted by the Most Reputable Brands in the World



NOVARTIS



Xybion Digital – Your Total SaaS Solutions Partner for R&D and Laboratory Operations

- Avoid multiple siloed systems
- Avoid IT infrastructure and resources inhouse
- Reduce upfront CAPEX significantly
- Drive digitization to avoid data issues and huge migration work later
- Better manager data, operate in full compliance, even if you are not a GLP operation, yet
- Xybion consulting can help strategize and implement Xybion software to achieve these

Dr. Pradip K. Banerjee
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Thank You



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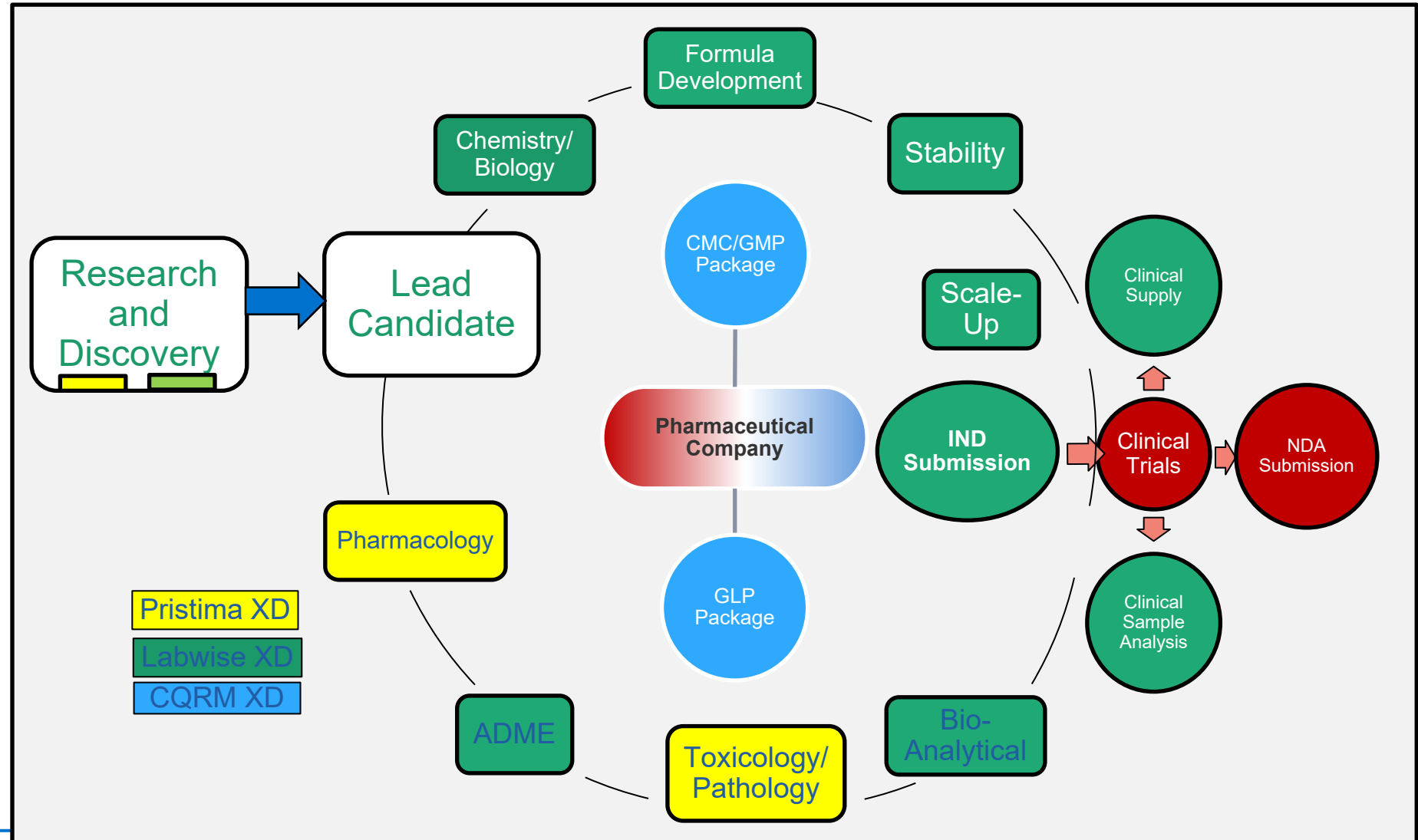
Appendix

Xybion Software and Solutions for Biotech

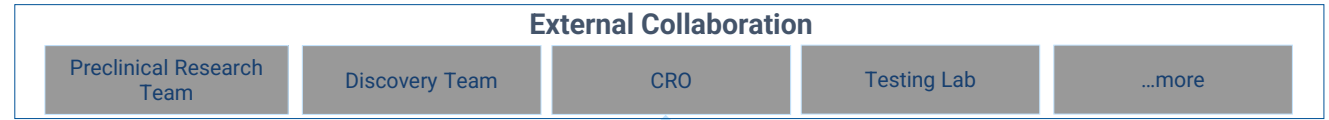
Our software cloud accelerates the conversion of inventions into approved medicines, saves lives, and helps keep employees safe.

How We Do It

- Our software can address the entire non-clinical process as shown by the color mapping of our software modules
- Our clients typically need 6-12 different software and manual steps to get finish each of the process bubbles shown on the right.
- Now, a single Xybion platform can replace/displace 6-12 different software and provide improved compliance and reduce costs



Lab Platform as a Service for Biotech – Cell & Gene Therapy LIMS



Xybion Client Portal



Business & IT Functions	Study protocol	ELN	Cell & Gene Lab mgt	CTSM	Lentivirus production	QC Process	Stability LIMS	Regulatory Submission	Review-Approval
	Animal Room	IACUC	ADME Profiling	Clinical Supplies Mgt	Investigator/Site Relationship	Analytical LIMS	MES*	Risk Management (REMS)	Contract Mgt
	Toxicology	Sample Mgt	Toxicology/Safety Assessment	Cell line Mgt	Electronic Patient Reported Outcomes	Complaints Management	OOS	Product Launch	EHS
	Histology	Inventory Mgt	Efficacy Screening	Lab request Mgt	Clinical Data Warehouse	BMR Review	DMS	Product Labelling Management	Incident mgt
	Data Mgt SEND	Pathology	Formulation Development	Protocol Design and Planning	Clinical Data Management	CAPA	Audits	PV	OSHA
	Vet Management	Formulations	Stability Study Mgmt	Portfolio Management	Medical Imaging	Process Monitoring	Process Scaleup	Product Registration	Billing/Invoicing
	HR	ERP- SAP/Oracle, etc.	Search	Knowledge Management	Content Management	Digital Asset Management	Collaboration	Records Management	Metadata Management
	Assets	Data Monitoring	Sample Assay Expression Suite	Warehouse	Data Lake	Biological Pathway System	R&D Data Lake	Clinical Trials Suite	Enterprise Data Management
	Planning/Cost Mgt	Case Management	Lab Instruments	Site & Patient Mgt	Lab Systems	IRT	Quality Mgmt. System	Analytics/Reporting	RIMS
	XDP	Form Builder	Workflows	Tasks	Dashboards	Audit trail	User Mgt	Admin	
Search		Rules	Security	API	Language	Codeset Mgt	...more		

Key

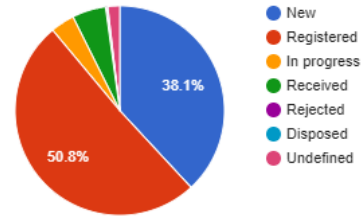
XDP Existing Capabilities	Integration	XDP Road Map
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Dashboard

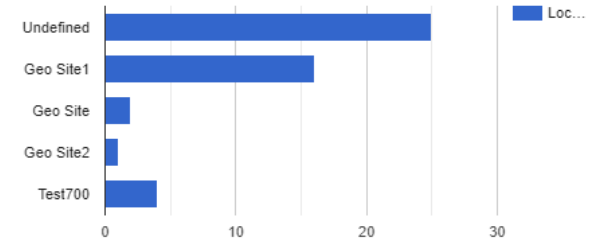
- + Support Modules
- + Equipment Calibration
- + Inventory Management
- + Sample Management
- + Test Management
- + Result Management
- + Study Management
- + Analytical LIMS
- + Storage Management Support Modules
- + IACUC Management
- + Quality Assurance Management
- + Study/Colony Registry
- + Request Management
- + Storage
- + QC Manufacturing LIMS
- + Diagnostic LIMS
- + Micro-Biology LIMS
- + CAR-T LIMS
- + Histology LIMS
- + Templates Records

Dashboard (General)

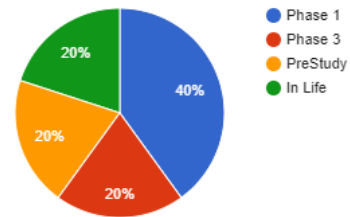
Sample By Status



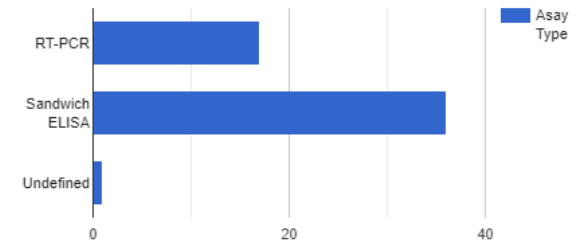
Sample By Location



Study Phase



Data Analysis




Cell & Gene Therapy / Personalized Medicine Lab Management


The Cell and Gene Therapy module includes:


- Assay Protocol
 - Titre determination
- Workflow execution
- Master Batch Record
 - Virus Production
 - Car-T production
- Sample Management
 - Sample Registry
 - Sample Storage
 - Print Labels
 - End to End visibility of Sample Movement
- Store files of different formats across the process
- Generate Reports
- Reviews and Approvals
- E-Signatures
- Audit Trail


System ID: 85 **Name:** Preparation of vector using plasmid XYZ


Lentivirus Production ▾ Details


 General Details


 Resources and Timeline

 Seed

 Transfection


 Harvest

 Report

 Review

Lentivirus Production ▾ Details ▾ Seed ✎ Edit 🔍 View Audit

Seed

Seed Date*
2020-12-15 

Details of Cells

Cell Type*	Cell Density (viable cells/ mL)	Viability	Passage Number
HEK-293T	5*10^6 cells/mL	97%	14

Add Cells to Media

Media	Media Catalog #	Media Lot #	Quantity (mL)
Material 002	CAT-1000	121	5mL

Production Vessel	Production Volume	Diluted Cell Preparation			Tube 1 (DNA)		Tube 2 (T5xR)		LV-MAX Enhancer
		Number of cells	Volume of Media	LV-MAX Supplement	Opti-MEM	Plasmids	Opti-MEM	LV-MAX Transfection Reagent	
1-Liter shaker flask ▾	400 mL	1.60e9	340 mL	20 mL	20 mL	400 ug	20 mL	2.4 mL	16 mL

ELN - Electronic Lab Notebooks

Labwise® XD A modular, integrated, and inclusive end-to-end Business Process Management (BPM) platform that supports all workflows in the lab, including test methods, Laboratory Information Management Systems (LIMS), Electronic Laboratory Notebooks (ELN), Quality Management Systems (QMS), Electronic Communication Network (ECN) and client portal.

Lab Diary®, a cutting-edge ELN solution from Xybion® enables facile, intuitive, user-friendly electronic documentation system for data management, collaboration and integration with laboratory information management (LIMS).

- Manage multiple Experiments in a Lab Diary
- Share Lab Diary with a specific set of users and have secured Access to Lab Diary
- Competency Compliance Check to ensure only compliant users can conduct and manage experiments
- Add and manage multiple Notes to an experiment - Allows scientist to capture notes during experiment execution.
- Import instrument output and store data recording at the experiment level
- Able to view the step-by-step process in the protocol document while conducting experiments
- Ability to link a Lab Diary to a Project / Protocol execution - Easy access to Lab Diary data related to a Project/ Protocol execution
- Linking to Inventory, Equipment, Sample allows to capture and track the material/ equipment and sample usage in an experiment
- Data import and export
- Analysis and dashboard
- Option to store multiple documents of different format in Lab Diary
- Record Deviations at the Experiment Level
- Manage review and approvals of the Lab Diary and Experiments
- Generate Report for an Experiment and /or for Lab Diary
- E-Signature enabled
- Active Audit Trail of all activities in a Lab Diary

The screenshot displays the Labwise XD Lab Diary interface. On the left is a sidebar menu with categories like Support Modules, Equipment Calibration, and Study Management. The main area features a 'Sample By Status' pie chart and a 'Study Phase' section. Below the chart, there's a form for 'Name/ Title*' (Antimicrobial susceptibility testing) and 'Project*' (Project-985-3). A 'Diary Owner*' field shows 'V Suresh'. A 'Lab Diary Status' dropdown is set to 'Draft'. Below this, a 'Diary Owner Core Training Status' is shown as 'Completed'. A table provides details for the project owner and start/end dates. At the bottom, there are buttons for 'Shared With' and 'Unlink Records', followed by a table listing users and their core training status.

Select	First Name	Last Name/Surname	Email	Core Training Status
<input type="checkbox"/>	Dhanashri	Gudi	dgudi@xybion.com	Completed
<input type="checkbox"/>	Muhammed	Ismail	mismail@xybion.com	Completed

Labwise® XD is a QC LIMS with sample management, inventory management, test method management, certificate of analysis and client portal for internal and external collaboration.

Test Method Management

- Test methods
- Product Management
- COA Mgt: USP/BP, etc.

Sample Management

- Sample Registry
- Sample Storage
- Print Labels
- End to End visibility of Sample Movement

QC Test

- Instrument calibration
- Test runs
- Final runs
- Test results
- Certificate of Analysis

- Certificate of Analysis
- Integration with other systems such as ERP and MES
- Reviews and Approvals
- E-Signatures
- Audit Trail

General Details		General Details			
Sample Registry		Certificate Of Analysis			
Sample Storage					
Sample Preparation					
Test Assignment					

Sample ID	SM-002370	Batch ID		Request ID	REQ-1212
Sample Type	Cell Line	Protocol No.	PT-STU-9068	Storage Condition	-20C
Total Volume	500 ul	Available Volume	500 ul	Sample Status	Completed
Expiry Date	2021-12-31	Registered By	admin_analyticalims	Registered On	2020-12-22 07:30:12 PM

Storage Details					
Storage Site	Resilience	Storage Room/Building	Building 101	Rack	Rack-001
Plate	Box-R1-001	Temperature (°C)	-20	Storage Location	A1

Associated Child Samples

Material Details

Total number of material: 13

Product Name	Product Number	Catalog Number	Molecule scheme	CAS #	Action
(R)-(+)-Pulegone	818885	818885-10		46022-05-3	
1,2,3,4,5-Pentamethylcyclopentadiene	818534	818534-5		4045-44-7	
Acetone				67-64-1	
Benzofuran				56-93-9	
Chloroform				1079-66-9	
Concentric					
Ethyl butyrate				105-54-4	

Inventory Details

Product Name: Ethyl butyrate | Product Type: Finished Product | Molecular Structure: CCC(=O)OCC

Product Number: 800500 | Inventory ID: 188543

Description: Type here or click the microphone icon for dictation

Main Details

Category: Chemicals | Sub-Category: In-Organics | Manufacturing Date: 2020-11-09 | Expiration Date: 2024-03-18

Catalog# : 800500-50 | Lot# : 188543 | Rate (g) : 25.00

Quantity on Hand: 55 | Volume/Quantity: 50 | Unit: ml

Administrative Site: Lynda Therapeutics

Notes: Type here or click the microphone icon for dictation

Barcode

System ID : 246
 Product Name : Ethyl butyrate
 Lot # : L65543
 Quantity/pack : 50
 Catalog# : 800500-50
 Manufacturing Date : 2020-11-09
 Expiration Date : 2021-03-18

Inventory Management

- Product Management
- Material Management
- Reagent preparation and management (inhouse)
- Material Reconciliation
- MSDS Management
- Automated Inventory updates
- Purchase Notification
- Order, receive and track inventory
- Search inventory using faceted search including chemical structure
- Track available, reserved, and consumed inventory
- Track date reserved, date used, and date created
- Be notified of any material that will expire within a specified number of days or of depleting inventory.
- Prevent usage of expired inventory in lab execution process
- Capture unit costs, ordering instructions, re-order amounts, and shipment details
- Automatically decrement inventory upon usage in lab execution process or upon fulfilling orders
- Audit Trail
- Review- Approval

Inventory

All Inventories Enter Search Term Q Search Q Advanced Search ?

Total number of inventory: 15

Product Name	Product Type	Quantity on Hand	Unit	Action
Ethyl butyrate	Finished Product	0	mL	🗑️
Concentrated Streptavidin HRP	Raw Material	10	case	🗑️
Microtiter Plate	Raw Material	45	case	🗑️
Pipette Tips	Raw Material	30	pack	🗑️
TMB Substrate Kit	Raw Material	240	pack	🗑️
Ethyl butyrate	Finished Product	955	mL	🗑️
Sodium formate	Finished Product	5980	mg	🗑️
Sodium acetate	Finished Product	6220	mg	🗑️
(R)-(+)-Pulegone	Finished Product	0	mL	🗑️
Chlorodiphenylphosphine	Raw Material	0	mL	🗑️

System ID : 246 Quantity on Hand : 955 Item Name : Ethyl butyrate Status : New Administrative Site : Lyndra Therapeutics

Inventory ▾ Details ▾ General Details

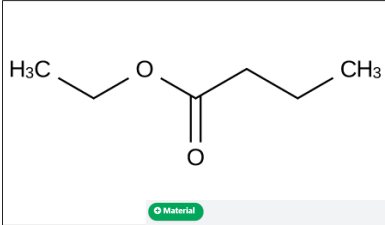
Inventory Details

Product Name: Ethyl butyrate Product Type: Finished Product


Product Number: 800500 Inventory ID: GHEM-2021-04

Description:

Molecular Structure



CCCC(=O)OCC








System ID : 246
Product Name : Ethyl butyrate
Lot # : L65543
Quantity/pack : 50
Catalog# : 800500-50
Manufacturing Date : 2020-11-09
Expiration Date : 2021-03-18

Material

Material Details Enter Search Term Q Search Q Advanced Search ?

Total number of material: 13

Product Name	Product Number	Catalog Number	Molecule scheme	CAS #	Action
TMB Substrate Kit	P901257	CT09812			🗑️
Microtiter Plate	8210112	CT3214			🗑️
Pipette Tips	P20851	RP01168			🗑️
Concentrated Streptavidin HRP	P12091	CT2109			🗑️
Ethyl butyrate	800500	800500-50		105-54-4	🗑️
Sodium formate	106443	106443-50		141-53-7	🗑️
Sodium acetate	106266	106266-25		127-09-3	🗑️
(R)-(+)-Pulegone	818665	818665-10		46022-05-3	🗑️
Chlorodiphenylphosphine	810158	810158-50		1079-66-9	🗑️

Patient Registration and Sample Management

The Diagnostic Lab module includes:

- Patient Registration
- Sample Collection and Submission
- Sample Registry
- Sample Processing
 - Batch creation
 - Plate mapping
- Instrument Integration
- Data Analysis
- QC Reviews
- Generate Reports
- Reviews and Approvals
- E-Signatures
- Audit Trail


Batch ID : BT-0000158

Batch Type: PCR Plate mapping Batch Status: Completed

Batch Creation: Samples-Search Samples - Scanning

Sample ID	Sample Status	Sample Type
SM-01091-2	In Progress	RNA
SM-01093-2	In Progress	RNA
SM-01101-2	In Progress	RNA
SM-01109-2	In Progress	RNA
SM-01112-1	In Progress	RNA

Analysis Template: Fosun Analysis Template

Upload Analysis Data:  102020 IH R2D 2.xlsx

Process

ID	TI	Sample Type	Target	Sample Name	FAM	Cy5	JOE	ROX	Result Determined
1	A1	Positive		FC Pos ext	25.50	19.70	26.18	26.32	Positive Result
5	A12	Positive		FC Pos	25.93	N/A	26.17	26.82	Positive Result
9	B1	Positive		FC Pos ext	25.34	19.71	26.18	26.62	Positive Result
13	B12	Positive		FC Pos	25.72	N/A	26.45	26.87	Positive Result

Quality Management & Compliance



Global Search



John Smith

Workspace Administration

My Dashboard Scheduler DMS Audit Trail Global Search Query

Dashboard

Quality Management System

Product

Nonconformance

CAPA

Complaint

Audit risk

Audit Program

Equipment

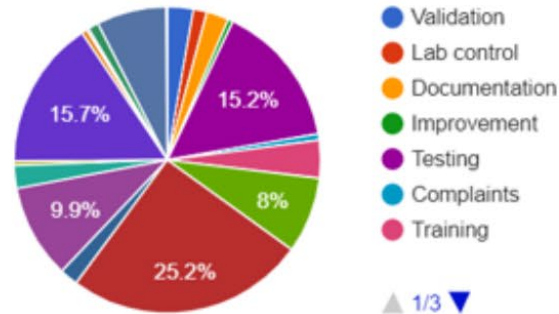
People/Org

Predictive Compliance

CP BaseLine DataSource

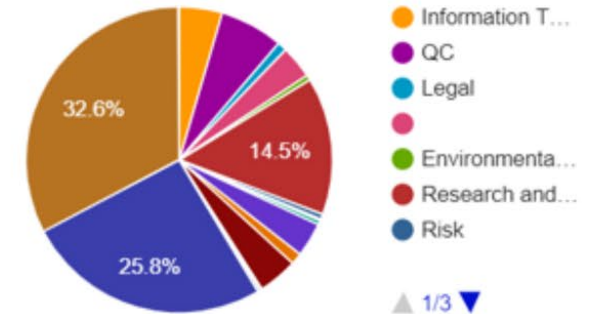
Import/Integration Records

Citation Classifications by Control Type



1/3

Citation Classifications by Function



1/3

Citation Classifications by Finding



Fines and Settlements - Countries



Document Management

- Allows documents templates to be created and used as needed to be filed into a user-configurable hierarchical “folder” taxonomy.
- Document permissions
- Check-in/check-out, versioning, rendering, approval, search and expiring document tracking capabilities with full text search and retrieval
- Automatic PDF conversion for any document in the repository.
- Ability to receive documents in multiple formats
- Tagging on content, metadata, documents and records
- Document tasks are sent to a centralized workload engine and notifications of status and other events are distributed to the user’s e-mail to facilitate timely completion of critical document activities.
- Allows users to embed internal document hyperlinks to support key regulatory processes requiring internal document links.
- Allows users to specify if documents are controlled or uncontrolled for good corporate governance.
- Create, review and approve documents
- Receive documents through scanners
- Records management for regulatory audits
- 21 CFR Part 11 compliance

The screenshot displays the QRM XD Document Management System interface. The top navigation bar includes 'Workspace' and 'Administration' tabs, with sub-menus for 'My Dashboard', 'Scheduler', 'DMS', 'Audit Trail', 'Global Search', 'Query', and 'CAPA (ID = CAPA7)'. The user 'John Smith' is logged in. The main content area is titled 'Internal Documents' and 'Document Version Search'. A search bar is present, and a table lists documents with the following columns: Name, Parent Folder, Checked out by, Checked out on, Owner, Updated on, Status, and Action. An 'Invoice Management' overlay is visible in the bottom right corner, showing a 'Study Details' section with a search bar and a table of study details.

Name	Parent Folder	Checked out by	Checked out on	Owner	Updated on	Status	Action
Corporate				5a5577f5b0412d6e464a611a	2018-03-20 11:31:45		
Corporate QMS							
Test							
	ACMECorp						
	ACMECorp						

Internal and external audit and risk prediction

- Dashboard
- Communication
- Data analysis
- Data analysis
- Setup
- Audit Execution
- Report & Follow-ups
- NC & CAPA
- Closure

Predictive Compliance
Xyblon Digital Platform
Global Search
John Smith ▼

Workspace Administration

My Dashboard Scheduler DMS Audit Trail Global Search Query Audit risk (ID = AUD-235) ✕

Unique Number: AUD-235 Audit Type: Vendor Audit Facility:

Name: Audit For demo CA Audit Sub Type: 3rd Party Audit

Audit risk ▾ Details

G

General Information

A

Audit Briefing Form

C

Communication

P

Previous Audit Results

Q

Questionnaire

R

Report

D

Dashboard

R

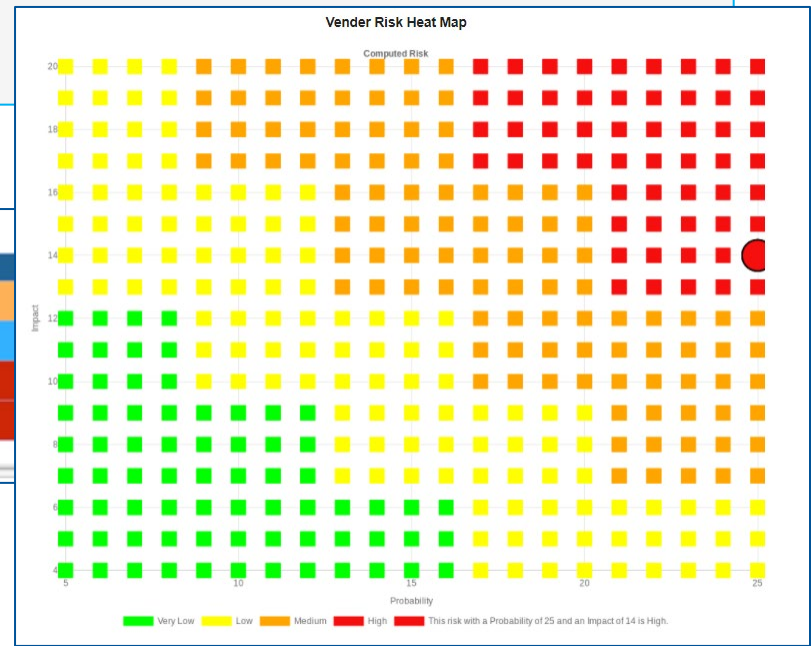
RCMM Report Level

A

Audit Action

Predictive Compliance Sample Report

Function/Control Types	Process	People	Quality	Technology	Governance	Investigation	Improvement
QA	0.27 Low	0.95 Very High	0.43 Medium	0.81 Very High	0.95 Very High	0.31 Low	0.79 High
Document Control	0.18 Very Low	0.70 High	0.95 Very High	0.13 Very Low		0.18 Very Low	0.33 Low
Facility	0.51 Medium	0.51 Medium	0.57 Medium	0.51 Medium	0.95 Very High		0.95 Very High
Materials	0.43 Medium	0.95 Very High	0.33 Low	0.95 Very High			0.95 Very High



Cost and invoice management

Invoice Management

Powered by Xybion Digital Platform

User Console Administration

My Dashboard Query DMS Audit Trail

Dashboard

- Grant Management
 - Grant
- Bill Management
 - Invoice
 - Study Details
- Support Modules
 - Organization
 - People
 - Customer
 - Product / Services
 - Contract Rates
- System
 - Interfaces

Study Details

Study Protocol Query

Total number of study details: 8

Customer

- Novartis
- GSK CA
- Chop Phill
- Pfizer
- Pfizer
- Novartis
- Johnson and Johnson
- Chop Phill

Showing 1 of 1

User Console Administration

My Dashboard Query DMS Audit Trail Study Details (ID = STU-3...)

Customer : Chop Phill
 Study Protocol : 1 Week Guinea Pig Study
 Nature Of Study : Animal

Study Status : Active
 Study Initiation Date : 01/21/2021
 Final Report Approval Date : 01/24/2021

Study Details ▾ Details ▾ Study Design

Study Design

Grant
Lab Grant-III

Study Protocol*
1 Week Guinea Pig Study

Study Status
Active

Study Initiation Date
01/21/2021

Duration (In Months)
8

Save

Bill To

Bill To Steve John	Address Line1 3102 Byron Center Ave SW	Address Line2 Joyce Street	City Gulf Shores
State California	Zip 36542	Phone Number 2519682540	Email chop@sponsor.com

Add Item

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2.	Animal Sample (Rat)	77	100.00	92.00	616.00	7700.00	⌵ ⬆ ⬇
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