# Quality **Research & Development** · Audit trails, electronic signatures, internal audits Internal/team collaboration · Complaints/incidents, NCRs, and CAPA investigations Environmentally sensitive labs and workrooms cell banks, trial sites and more) **Supply Chain** IP protection SOP management and compliance monitoring Stability and re-test quality testing Demand forecasting / Movements and transfers quality testing Contract employee engagement Quality audits management Management of controlled documents Optimizing inventory balances Replenishment activities Labeling

- Scientific collaboration (CROs, CMOs.
- Partner collaboration (Investors, vendors, peers, market opportunity)

We understand the unique needs and processes of life science organizations.



## Manufacturing

- Weighing and dispensing
- · Electronic batch reporting
- Electronic device history reporting
- Equipment monitoring, maintenance and calibration schedules
- Finished product testing, conditional release, and final release
- Qualified resource scheduling controls
- Collaboration with CMOs, CDMOs, CROs

## **Inventory & Warehousing**

- Finished goods stability, expiration and re-test
- Integrated labeling, shipping, and tracking
- Mobile apps enabled
- Segregate inventory by intended use and quality levels
- IoT environmental monitoring
- Critical materials track and trace
- Controlled storage conditions
- Batch/lot/serial registration and tracking
- Unique Device Identifier (UDI) tracking and label generation
- Batch/lot splitting and genealogy

# External Influences

# Microsoft Cloud

Familiaruser experiences

**Human Resources** 

and Payroll

• Design, development and delivery of training program Training compliance reporting

Secure employee/employer

Training compliance

Workforce training

administration

documents

- Native application integration
- Microsoft Trust Center (GAMP, SOCS, FDA, etc.)
- Disaster recovery and system redundancy

**Customer Relations** 

• Flexible customer

engagement models

for pharma, biotech,

· Multi-dimensional customer

and partner relationships

Controlled and restricted

and medical device

substance controls

- Zero trust foundation
- Secure hybrid workforce
- All based on the Azure platform

# **Finance**

capacity planning

Stability and retest

quality planning

Oualified resource

scheduling Intercompany supply

and demand

Quality planning

- Project accounting for custom, commercial, and R&D activities
- Actionable financial views on operations and investment strategies

• Manufacturer certifications and vendor classification levels

Royalty and revenue recognition processes

**Procurement** 

· Vendor certifications, vendor audits and approvals

quality inspections

· Raw materials labeling, release,

Vendor performance management

Supply chain risks assessment

Product and project costing

### **COMPLIANCE**

- GAMP, cGMP, FDA, DEA, ISO, NIST, ANSI, UDI
- FED, STATES, Benefits
- GAAP, IFRS, SSAE, SOC1-3, Sarbanes-Oxley, Sunshine Act reporting

#### **PARTNERS**

- CMOs, CDMOs, CROs, Cell Banks, Clinical Trial Sites, Contract/ Vendor Employees
- IVV
- Benefits, recruiters
- 3PLs
- M&A, Private equity