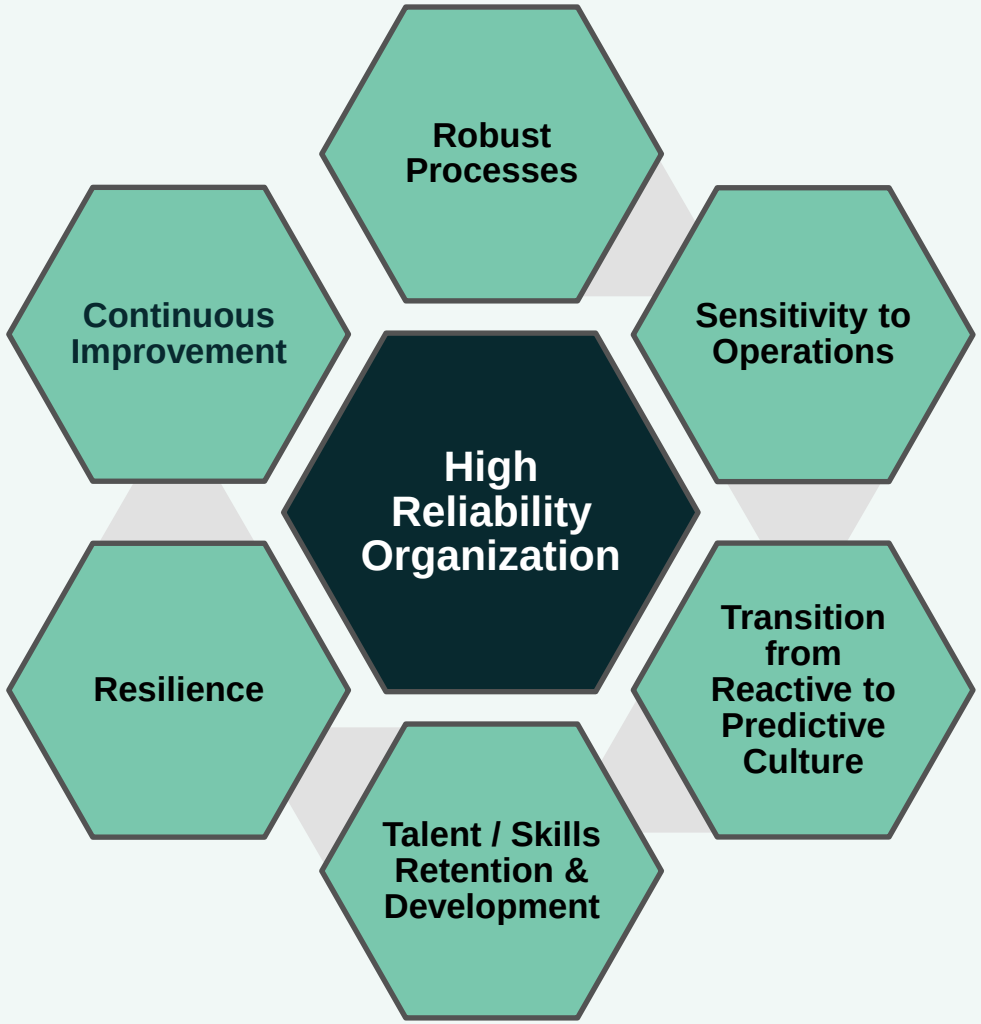
Selkirk

A New Contract Manufacturer for Injectable Drug Product


MADE IN
USA
Selkirk
Selkirk
Spokane, WA

Built for Quality, Reliability, & Speed

Customer Trust	• Foundational Partnerships • Integrity
Consistent Quality	• Right-First-Time • On-Time and In-Full
Reduced Cost	• Minimize Rework • Optimize facility Operation
Compliance and Safety	• Regulatory compliance history • Safer work environment



Pledge: We make your success faster and certain!

Manufacturing Capabilities

Our Facility

- 115,000 sq ft Plant 1
- Modular cleanrooms
- Unidirectional flow for personnel, components, equipment and products
- 15,000 sq ft of controlled temperature and refrigerated storage.
- Frozen storage capacity (-20°C & -80°C)
- Dedicated/disposable filling systems
- Annex 1 compliance

Line 1

- Bausch and Strobel VarioSys filling system with SKAN isolators with integrated vial rinser and depyrogenation tunnel
- 1 – 400 L Capacity
- Bulk vial filling - 0.5 mL - 50 mL
- Vial sizes: 2R – 100R
- Up to 3,600 vials/hour
- Advanced Fill: 99%+ recovery
- Minimal line loss (as low as 100mL)
- Nitrogen headspace capability

Manufacturing Capabilities

Line 1 (Con't)

- Vaporized hydrogen peroxide (VHP) decontamination
- In-line 100% non-destructive weight checks
- Rotary piston and peristaltic pump filling options
- Compatible with Ready to Use (RTU) stoppers and overseals
- Annex 1 compliant
- Bulk packaging

Inspection

- 100% Visual Inspection
- Illumination intensity of 2,000 – 3,750 lux
- In-house Defect Kits

PIP Offices

- 3 dedicated offices
- Camera visibility

Line 1 Manufacturing Floor

Blue – Analytical Labs
Dark Green – CNC
Light Green – Grade C
Grey – Grade D
Orange – Grade A (Filler)

Bausch and Strobel VarioSys filling system

1. Vial Rinser
2. Depyrogenation tunnel
3. Filler, Stopper, Oversealer
4. Tray-off Isolator

Analytical Capabilities

Services

- Method Transfer & Compendial Method Verification
- Raw Material Testing (USP/NF, EP, JP)
- API, In-process & Filled Vial Testing
- Qualified External Laboratories for Outsourced Testing

Instrumentation

- Chromatography
  - Waters Arc HPLC Systems with UV/Vis detection
  - Agilent 8860 GC with FID & TCD
  - Waters Empower Chromatography Data System
- Spectroscopy
  - Mettler Toledo UV7
  - Thermo Fisher Nicolet FT-IR
- Additional Instruments
  - Mettler Toledo SevenExcellence pH/Conductivity Meters and XPR Analytical Balances
  - Sievers M9 TOC & Conductivity Analyzer
  - Beckman Coulter HIAC Subvisible Particulate Analyzer
  - Precisions Systems Osmometer

Microbial Capabilities

Test	Method
Endotoxin Testing - Kinetic Chromogenic	USP 85
Sterility Method Suitability (B&F)	USP 71
Bioburden Method Suitability	USP 61/62
Microbial Examination (Bioburden)	USP 61/62
Microbial Identification	USP 1113
Microbial limits (Excipients/Raw Materials)	USP 61/62
Isolator - Sterility Testing	USP 71

Systems & Equipment

- MODA-EM
- 3P Enterprise Automated Plate Readers
- VitekMS Prime Microbial identification system
- Sievers Eclipse Bacterial Endotoxins Testing (BET) Platform
- Milliflex Oasis
- SKAN Spectra Sterility Isolator

Project Mgmt, Tech Transfer, and Warehouse

Project Management

- Qualified Project Managers with extensive experience
- Single point of contact

Technology Transfer

- Multi-disciplinary product transfer teams
- Facility and transfer processes designed to enhance client input and oversight
- Highly experienced subject matter experts dedicated to every project

Warehouse

- 15,000 sq ft of controlled temperature and refrigerated storage
- Frozen storage capacity (-20°C and -80°C)
- Best-in-class Manufacturing Monitoring System (MMS)
- Electronic Enterprise Resource Planning (ERP)
- Dedicated receiving and shipping departments

Technology Transfer

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Evaluation

- Client transfer package
- Facility Fit
- Safety evaluation

Process Development

- Create efficient and consistent processes
- Document creation including batch records, SOPs, and specifications
- Source new materials
- Training
- Engineering batches

Process Validation

- Develop validation strategy and plan
- Define acceptance criteria
- Execute validation studies
- PPQ batches
- Confirm consistent process, quality, safety
- Qualify any new equipment

Continuous Improvement

- Monitor transferred process to ensure compliance
- Look for opportunities make improvements

Pharma 4.0

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✓ Complete
❑ In Process

Digitized Processes

- ✓ TrackWise (dev mgmt)
- ✓ ABS recipe backup
- ❑ TULIP (logbooks)
- ❑ P2P (PO process)
- ❑ Connected 3P (plate read)
- ❑ OT file copy (machine batch info)

Smart Factory

- ✓ BMS (building monitoring)
- ✓ MMS (MFG monitoring)
- ✓ BMRAM (asset & calib mgmt)
- ✓ Card MGMT / Uni-flow
- ✓ Connected equipment
- ✓ Connected lab
- ❑ Batch record (form)
- ❑ LabX

Big Data

- ❑ DAS Pi (historian)

Business Intelligence

- ❑ Client Dashboards
- ❑ Knowledge Mgmt
- ❑ Metrics and KPIs

Selkirk's start of Pharma 4.0 through 2024

Regulatory Compliance

- ✓ DOT (DMS)
- ✓ MODA-EM (environ monitor)
- ✓ QAD (inventory control)
- ✓ QAD (prod orders)
- ✓ REDICA (reg surveillance)

Data Integration

- ✓ BOOMI (ESB)
- ❑ QAD<> BMRAM

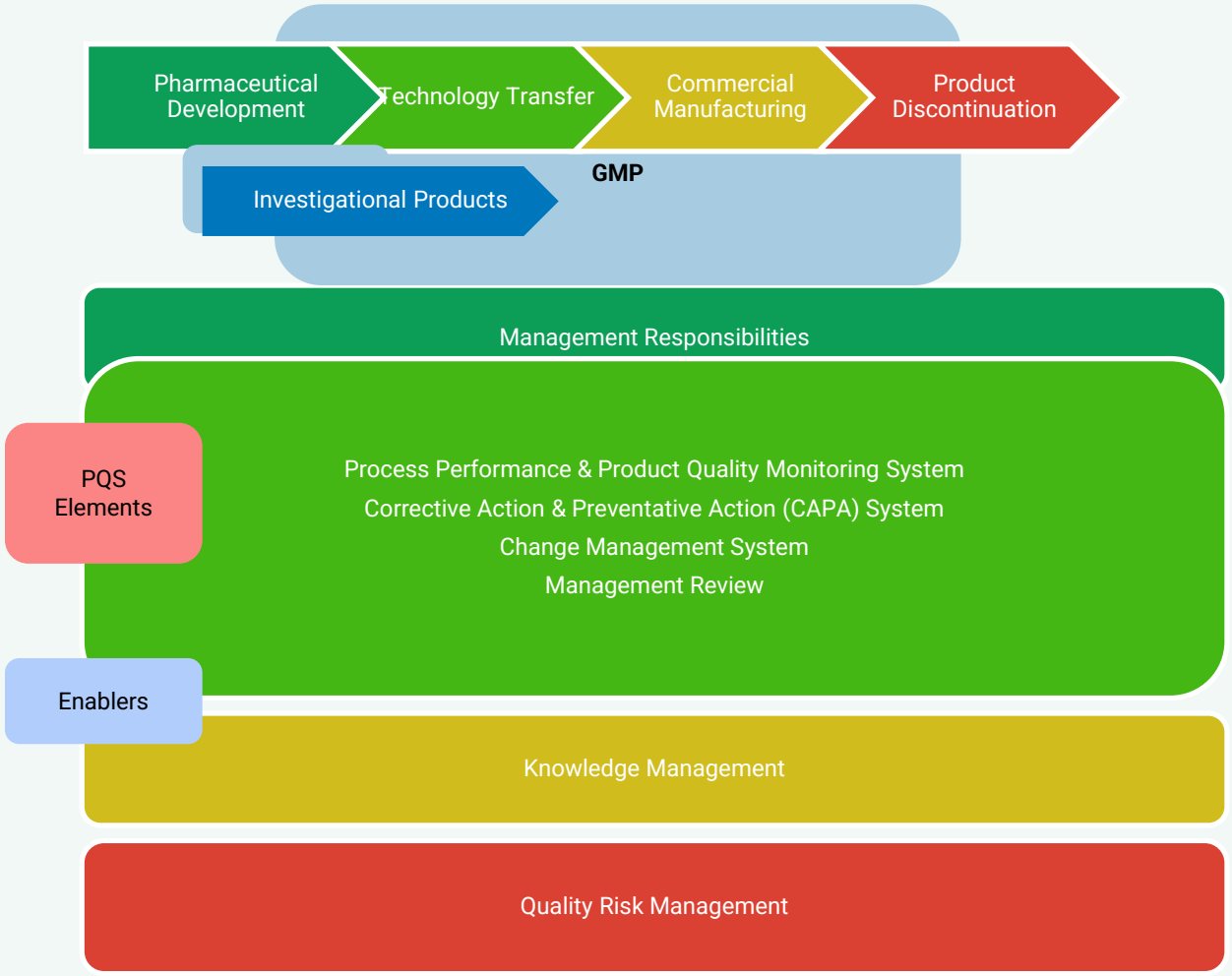
Infrastructure

- ✓ IT / OT networks
- ✓ Backup verification / data recovery
- ✓ Penetration testing
- ✓ Server architecture
- ✓ DUO MFA

Quality System

- Foundational programs and systems based on ISO 9001: 2015 requirements and ICH Q10 /Q9.
- The QMS is not based on department roles but on cross-departmental systems and processes encompassing departmental roles.
- Selkirk defines, maintains, plans, and staffs an organization that can support the Quality Management System to meet all product and lifecycle phase-appropriate needs and regulatory requirements.
- Selkirk has self-identified programs that require updates and will continuously update procedures to ensure compliance and robustness.

ICH Q10



eQMS

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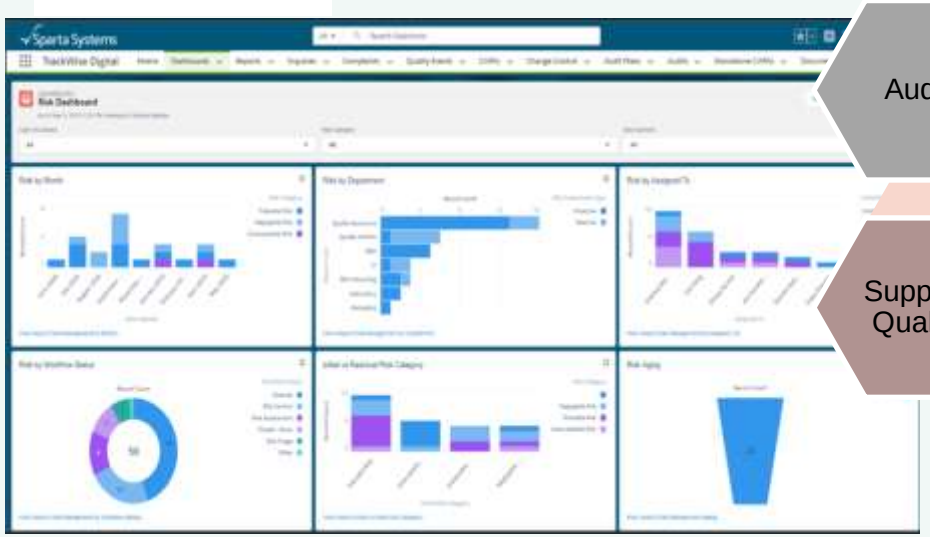
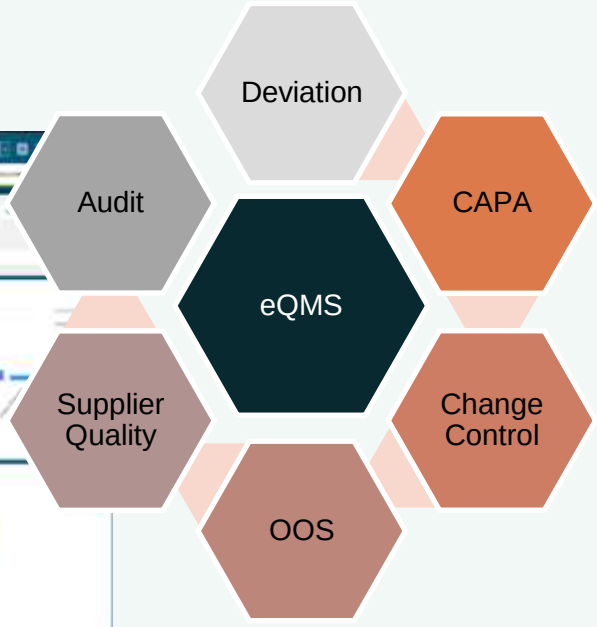
Dot Compliance

- *DOT Compliance Suite is a pure cloud Quality Management System being used for eDMS.*
- *The Dot Compliance solution is compliant with industry standards including 21 CFR Part 11 and the EU Annex-11*

TrackWise DIGITAL





- *TrackWise Digital is a cloud based Electronic Quality Management System.*
- *Compliant with industry standards including 21 CFR Part 11 and the EU Annex-11*

Regulatory Affairs - Priorities

Compliance

- **FDA Establishment Registration**
  FEI # 3015893397
- **Unique Entity ID**
  UEI # SF7UX8ZYKQW8
- **State Licensing**
  WA & 15 Non-Resident States
- **FDA Bulk Drug Listings**
  Selkirk Labeler Code
- **FDA Listed Drug Amount Reporting**
  Coronavirus Aid, Relief, and Economic Security Act

Per Client Demand:

- Small Business Registration, Alcohol, Controlled Substances, etc.

Regulatory Operations

- **FDA Pre-Operational Review**
  Pre-Construction (July 2020)
- **FDA Facility Drug Master File**
- **eCTD Publishing Software**
- **FDA Electronic Submissions Gateway**
- **Baseline & Mock Inspections**
- **CMC Review**

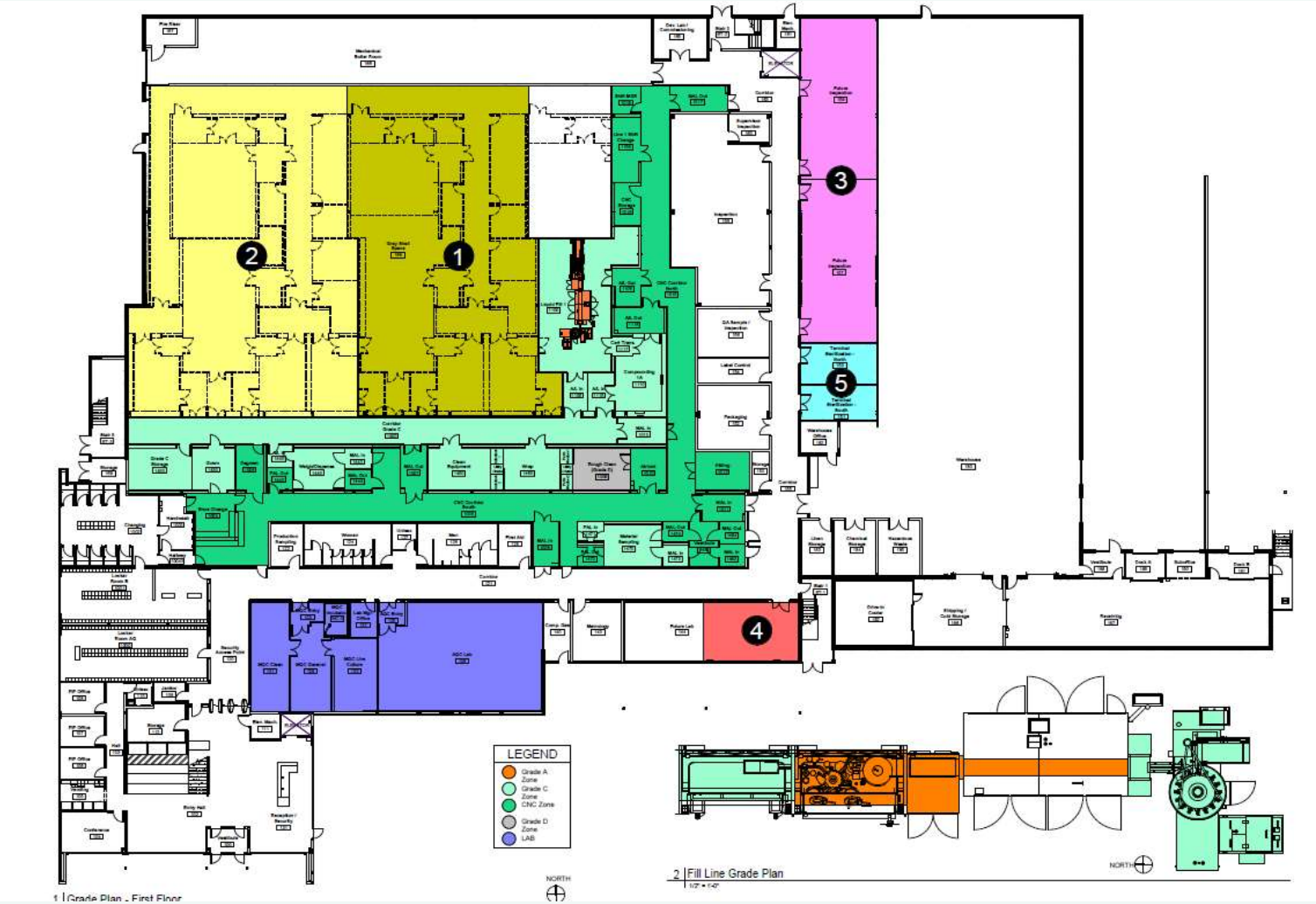
Per Client Demand:

- CMC Authoring
- FDA GDUFA Self-Identification and CMO Facility Fee
- EU Site Master File

Surveillance

- **Agency & Industry Monitoring**
- **Automated Regulatory Intelligence Platform**
  Guidance updates and enforcement

Plant 1 Expansion



Areas ❶ & ❷

- Two additional RTU lines for syringe, cartridge, vials

Area ❸

- Expanded Visual Inspection

Area ❹

- Stability Chamber Expansion

Area ❺

- Terminal Sterilizer Expansion

Plant 1 Expansion

RTU line for Syringe, Cartridge, Vials

- Manufacturing available in 2026
- Syringe fill volume 0.02 - 10 mL
  - 0.5 - 10 mL syringe
  - Up to 4,300 syringes/hour
- Total annual capacity all 3 lines: 45M units (vials, syringes, cartridges)

Additional Expansion Plans

- Automated, Semi-Automated Inspection - 2025
- Stability Chambers – 2025, or earlier based on client needs
- Terminal Sterilization – 2026, or earlier based on client needs

Campus Expansion

19 acres of adjacent land for future growth

Plant 2:

- 110,000 sq ft
- High-Speed Filling
- Prefilled syringes and cartridges
- Total annual capacity: 400M units

Plant 3:

- 125,000 sq ft
- High-Capacity Vials and Lyophilization
- Total annual capacity: 70M lyo vials, 200M liquid vials

Designed for Contract Manufacturing

- Fully integrated, high yield Bausch + Strobel VarioSys flex filling lines
- State-of-the-art SKAN isolator system
- Best in class facility with unidirectional personnel and product flows
- Multi-disciplinary project teams dedicated to clinical and commercial product transfers
- Captured grey shell space for additional filling lines

Achieve efficient performance with an expert team in a new state-of-the-art facility

We’re Ready to Go

Vial Capacity Now Available

Thank you.

Selkirk