

BIOSPECTRA



Updates

New Products – Capital Investments - Sustainability

09-09-2023

New Products & Expanded Capacity

2023 & 2024:

1. Begin expansion of the new Canadian Operation – Dextran Products (see separate PP)
2. Continue with Sage (ERP) integration and Data Integrity Program
3. Finish conversion to Electronic Batch Records
4. Continue with Utility Overhaul as part of the Sustainability Program
5. Finished Upgrades to Tris HCL Production Suite M11
6. Complete construction and Validation of J1 Manufacturing Suite
7. Expand Tris, Urea, MES, HEPES, Trehalose and Galactose Capacity
8. Complete M05 P32 Spray Dry Suite for Free Flowing Tris
9. Complete M12 for additional Chlorination capacity
10. Complete in-house HCL Gas Generation
11. Complete C22 Hastelloy P50 Spray dry Suite for Free Flowing THCL
12. Finish re-construction of S05 Suite Stroudsburg, GHCL Suite
13. Finish outfitting BDI in Rensselaer NY
14. Continue with Supply Chain Security and Sustainability Programs

Recently Completed

- Trehalose Dihydrate Expansion
- 2MEA (Cysteamine HCL) Expansion
- Galactose Expansion
- L-Cystine Di HCl Expansion
- Bis-Tris
- Uridine Expansion

New Products & Expanded Capacity

Coming in late-Q3/Q4/Q1 2024

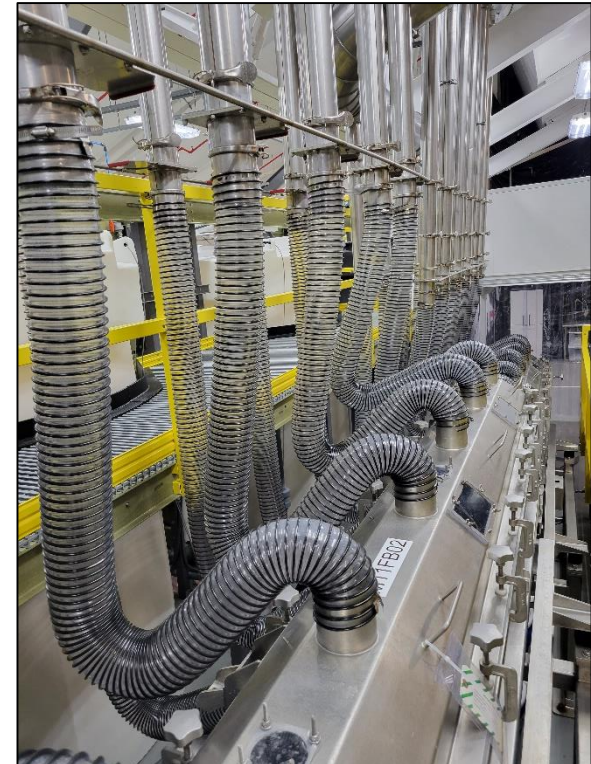
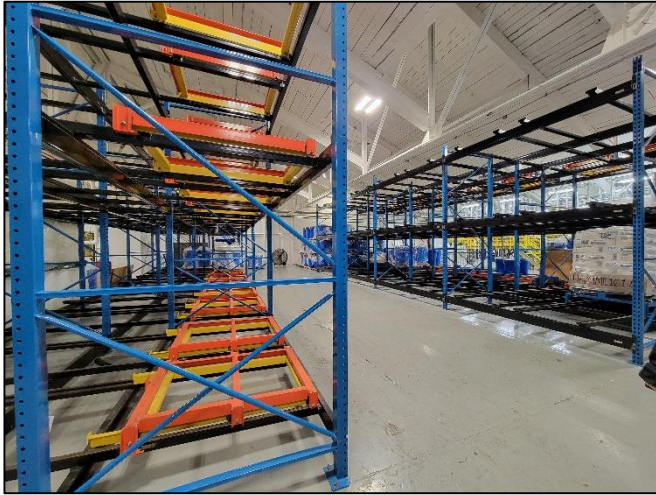
- Dextran Sulfate 8000
- L-Arg HCl
- L-Glutamine
- BIS-TRIS HCL
- Synthetic Parenteral Glycerin
- Uridine API
- Cytidine API
- L-Histidine Monohydrochloride, Monohydrate
- Dextran 70,000
- Na Decanoate (expansion)

New Products & Expanded Capacity

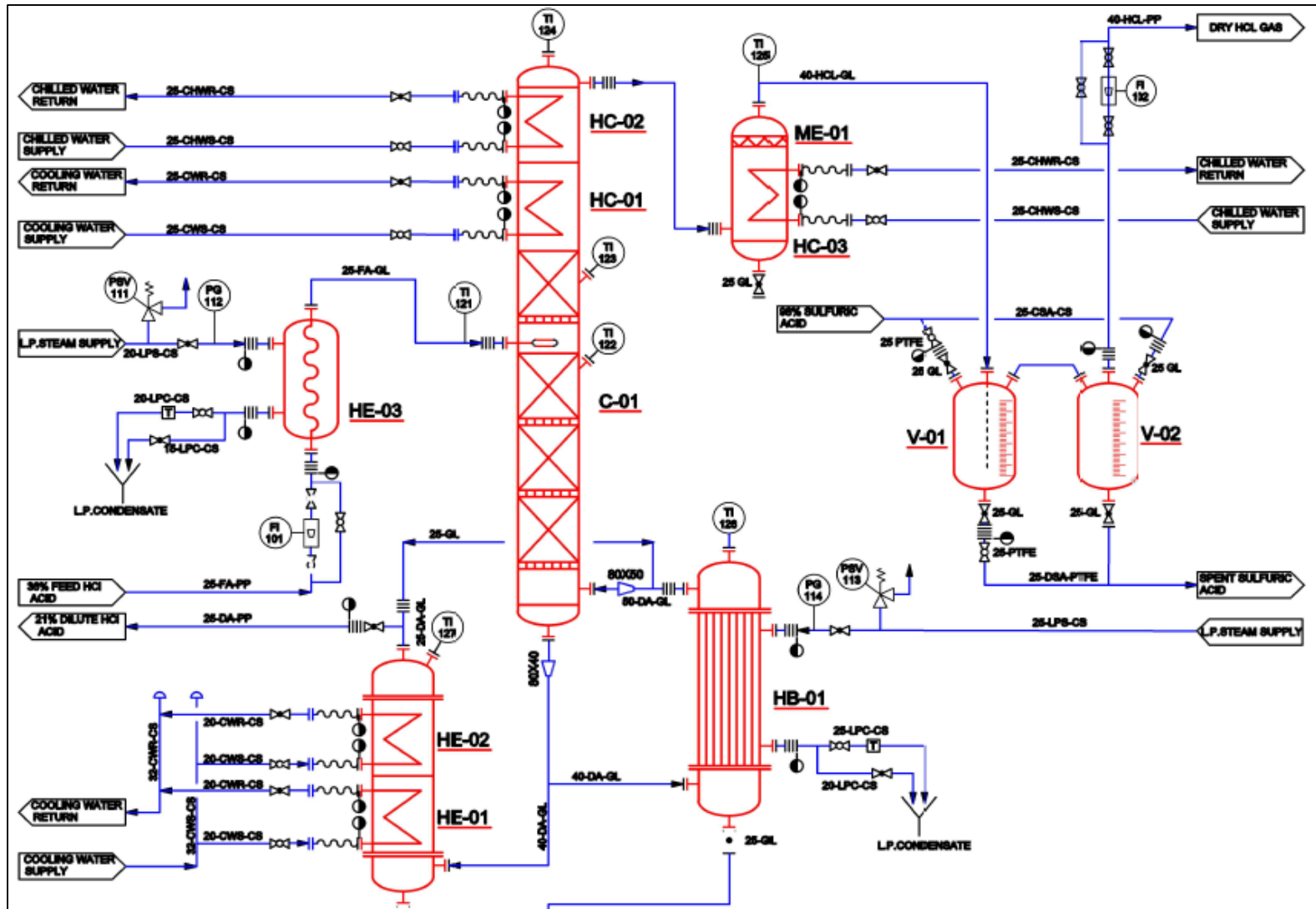
Coming in 2024

- L-Cysteamine API
- L-Histidine Parenteral
- Synthetic Trehalose Dihydrate API & Excipient
- Free Flowing Tris & Tris HCL
- Free Flowing Urea
- Dextran 40,000
- Dextran Sulfate 10,000
- Synthetic Cholesterol Excipient Grade

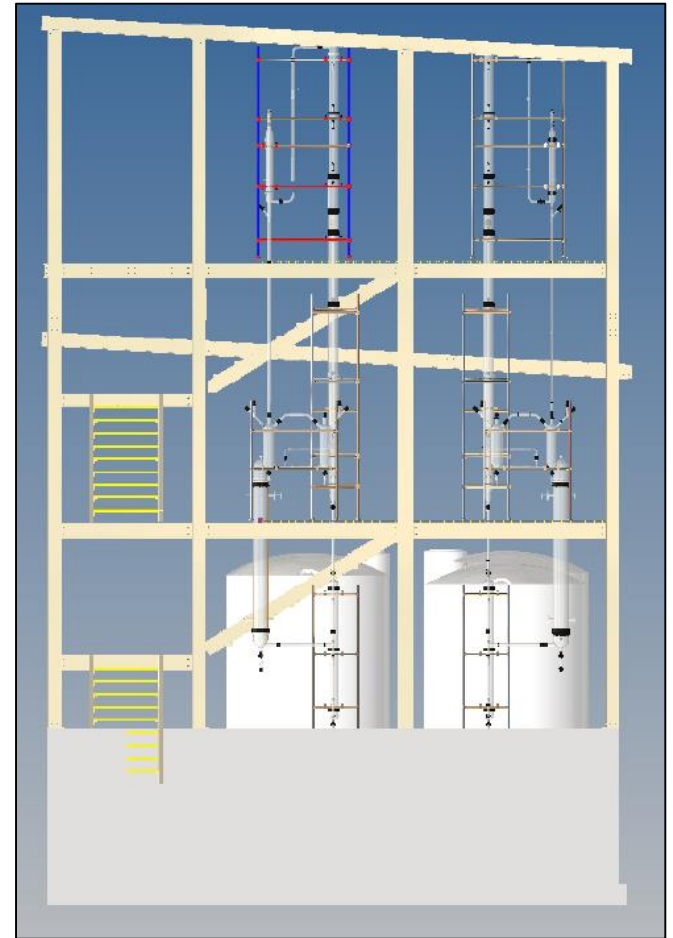
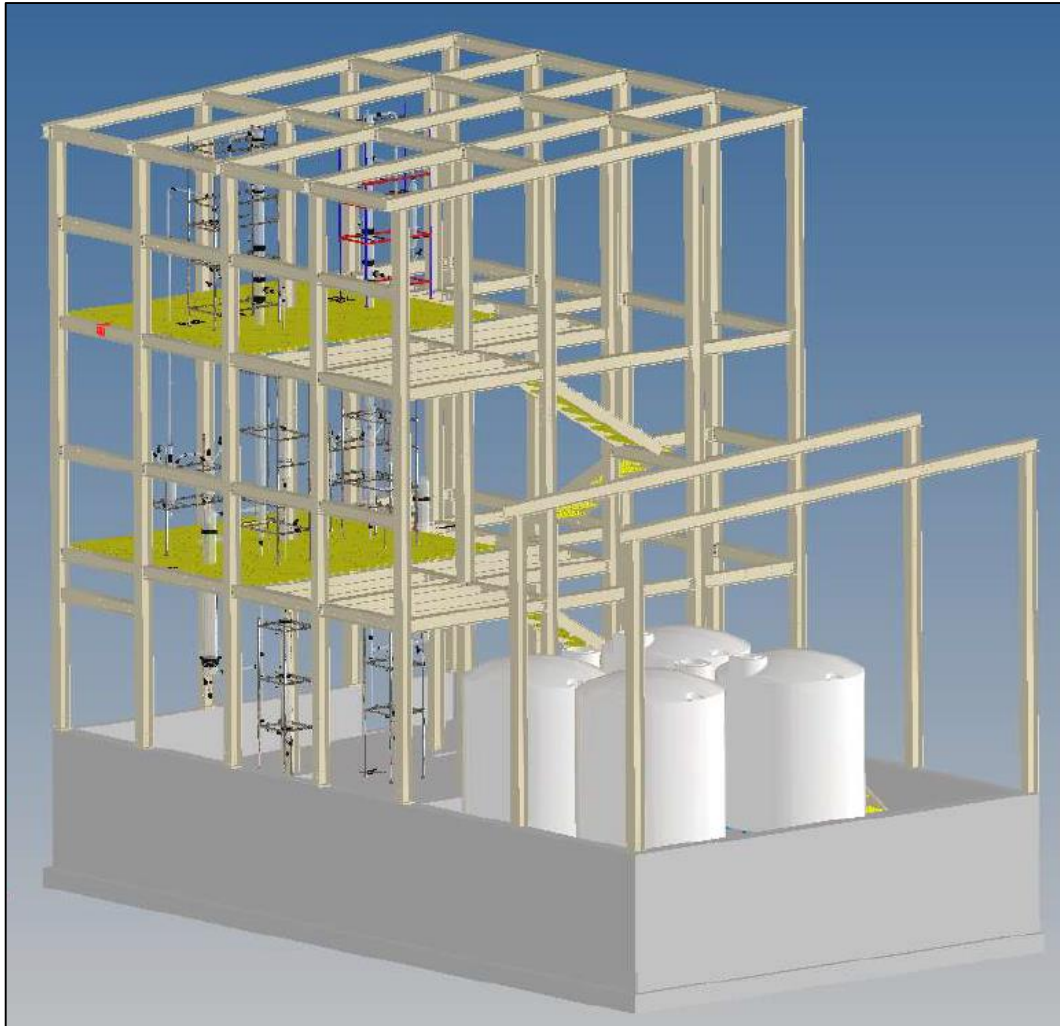
Bangor – M12 New Process Suite



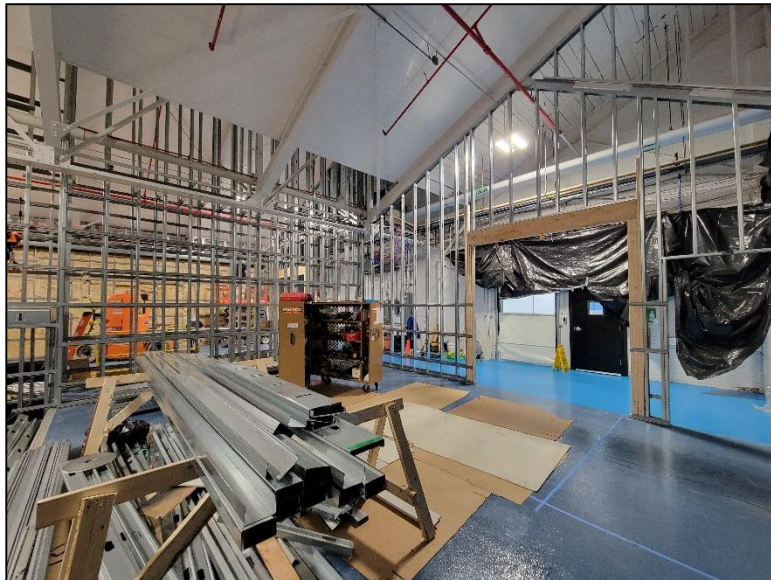
HCl Gas Generation System – P&ID



HCl Gas Generation System – 3D Model



Spray Dryer Suites — Model 032 & 050 Hastelloy



Canadian Acquisition



1. Modernize and expand GMP Dextran Products
2. Supply Chain Security for China RM's
3. Additional products coming with new Mfg capacity and patents

AMES Building



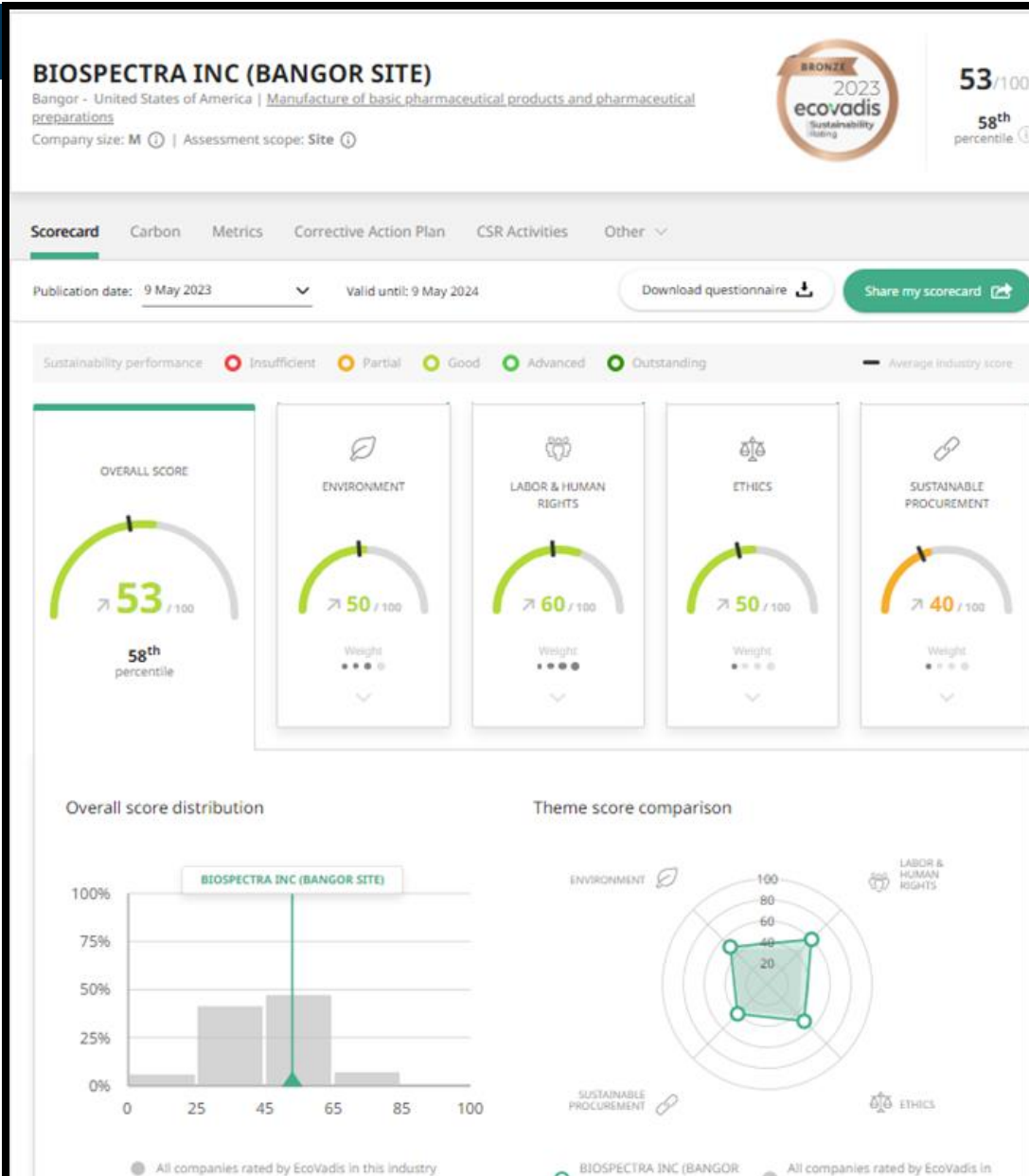
1. Wet Labs
2. Inbound Modernize and expand GMP Dextran Products
3. Supply Chain Security for China RM's
4. Additional products coming with new Mfg capacity and patents

BIOSPECTRA

Sustainability Program Phase II

09/09/2023 v.1.5

Sustainability Program



Sustainability Program

Assignment

I. Environmental

A. SOP on “Environmental Practices & Mitigation Program”

1. Include in SOP details we do not discharge API’s into the water or general environment
2. Include in SOP – policy to assess each new operation / change for environmental impact.
3. Include in SOP - regarding Noise and personal protection
4. Include in SOP the current SOP on Dust and/or particulate matter controls
5. Include in SOP, requirement to document work process to mitigate odor, noise / use of filters for same
6. Include in SOP, any program to separate and reduce waste
7. Include in SOP all items below that we decide to do

B. Tracking Normal Waste:

1. Compile 2022 data
2. Tracked (metrics) - ratio to production output / volume of people.. (Bangor plant only)
3. Establish KPI’s

C. Tracking Renewal (recyclable) waste outputs

1. Compile 2022 data if possible
2. Metrics (Bangor Only) – ratio to outputs
3. Establish KPI’s

D. Tracking Hazardous Waste

1. Compile 2022 data if possible
2. Metrics (Bangor Only) – ratio to outputs
3. Establish KPI’s

E. Crystal Recovery

1. Compile 2022 data if possible
2. Metrics (Bangor Only) – ratio to outputs
3. Establish KPI’s

F. Water Consumption

1. Compile 2022 data if possible – ration to outputs
2. Metrics (Bangor Only) – ratio to outputs
3. Establish KPI’s

G. Tracking Air Emissions – GHG’s (Green House Gasses)

1. Total Emissions – ratio to outputs
2. CO2 Separately – ratio to outputs

H. Noise Monitory (external) – at site boundaries

I. Energy Consumption *

1. Total consumption relative to outputs
2. Analysis and tracking of % renewable
3. Track project and results of projects that reduce energy consumption (through PMO)

J. POP Statement of non-emission - VOC, SO2 NOx or heavy metals

Sustainability Program

I. Employee Health and Safety

A. SOP for Health and safety training for Sub Contractors – add a training module in MC or Compliance Wire

A. SOP on Employee Health and safety that includes:

1. demonstrates a review of all health and safety features when changes are made.
2. Safety committee
3. Two-way communication system to facilitate employee voice in regard to employee health/safety and working conditions -
4. Requirement for Loss Time Injury reports
5. Requirement for reporting of any health and safety issues (incident reports)
6. Requirement for Employee Satisfaction Survey

A. Loss Time Injury reports, data, KPI

A. Safety Committee Charter / By-Laws / Minutes of meeting and schedule list of meeting with signatures

A. Incident Reports (Health and Safety) – Metrics/ KPIs

A. Employee Sat. Survey – metrics

I. Human Development

A. SOP on Ethics – NEO: includes: bribery, corruption, money laundering, acceptance of gifts, conflicts of interest, Fraud, Anti-Competitive practices, Adherence to all Law and regulations governing the export/import of Chemicals include the country of destination (respect all laws) – NEO

A. Training Module on Ethics – NEO: includes all the same items above – at a minimum this is mandatory for anyone in Finance and Supply Chain with purchasing power

A. Training module on Environmental practices – NEO (see SOP above) – MC

A. Training module on Labor Practices – NEO: Child Labor, Forced-labor and/or human trafficking – MC. This can be a PP presentation we put together and bundled with our NEO

A. Training Module on Sustainability Program – NEO and practices – MC Mirrors SOP above

A. Training Module: self Improvement program – NEO

A. Metrics and KIP's on percent employees trained on A-F

A. Metrics on External Educational support

A. Whistle Blower Program – corruption, fraud, theft, abuse other

A. Grievance mechanism for discrimination or harassment issues (PP, SOP, Policy) – MC (bundle with Sexual Harassment, hostile work environment

A. Average Hour of training (any/all) per employee/yr

A. Documentation of any “corruption incidents/yr

A. Documentation of Salary review and bonus program

I. Supply Chain (not included in other sections)

A. Statement regarding no use/incorporation of Tin, Tantalum, Tungsten or Gold

A. Policy on conflict metals

A. Cascade Conflict Mineral Statement to Suppliers – metrics

A. Cascade Supplier code of Ethics / Metrics

I. External Facing: Customs, Distributors, Suppliers

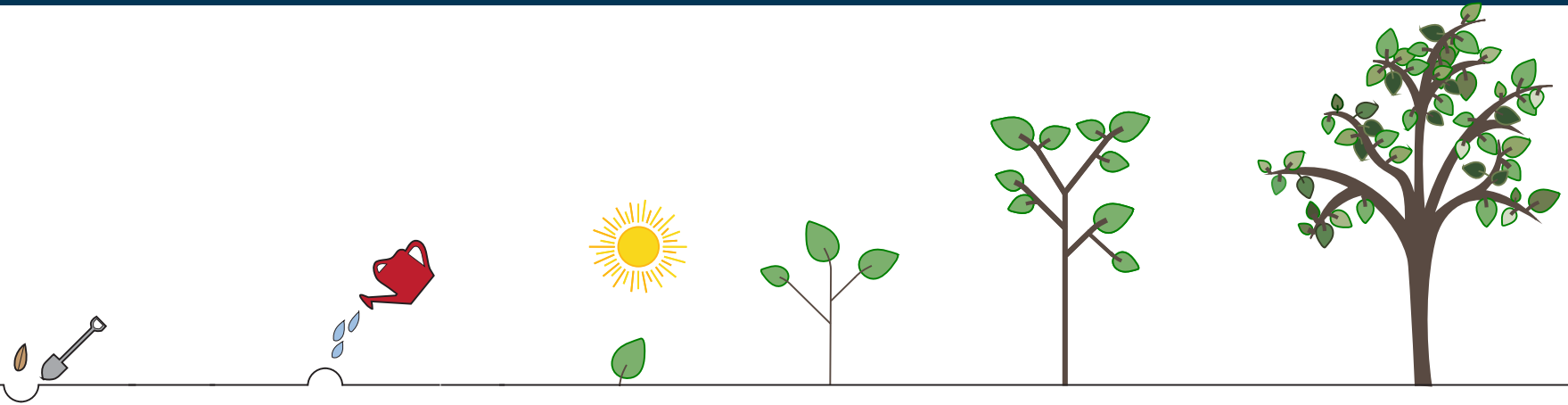
A. SOP that details how we protect a customer from our product:

1. SDS's
2. Safety date on labels
3. Intended use statements on CofA's, Technical sheets

A. Cascade of Code of Ethics for Commercial Partners (Distributors, Agents etc.) - Metrics

A. Inclusion of Human Rights and Labor practices in Contracts, Supplier Questionnaire and Supplier Audits

Our Company Growth



1993- The BioSpectra Organization was created on December, 26, 1993 and operated at the original site in Sciota, PA.

1995- BioSpectra Inc. (BSI) was incorporated in Pennsylvania, USA on September, 15, 1995

2001- BSI committed to opening the Stroudsburg, Rockdale Lane facility, the first U.S production site fully dedicated to repurified GMP Buffers.

2006- BSI created BioBuffer Solutions Brand to support the need for upstream materials to our critical customers.

2011- BSI acquired the much larger facility in Bangor, PA. Here to expand manufacturing and expand our portfolio of GMP Pharmaceutical Process Fine Chemicals, Excipients and API's

2019-2020- BSI acquired several other local properties to house external services such as Fleet for cars and trucks, buildings and ground equipment and non-controlled storage

2021- BSI opened the Corporate Services Center in Wind Gap, PA in April of 2021

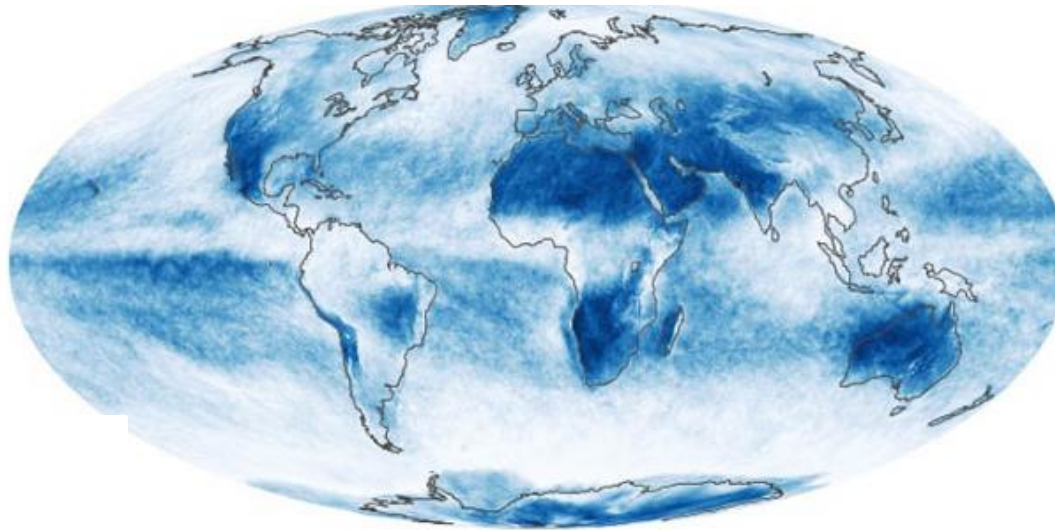
2023- In January of 2023 BSI opened the 60,000 sq. Ft. GMP storage facility at 3rd Street Stroudsburg, PA.

What's next?- BSI is busy working to expand our manufacturing footprint overseas as well. In 2024/2025 BSI plans to open another 80,000 sq. Ft. facility adjacent to our GMP Storage Facility to house our expanding analytical services and automated packaging operations and so much more!

Sustainability and Supply Chain Security

Sustainability

BioSpectra is committed to the ideals of Sustainability and has launched a three-year thirty million dollar capital investment program to help achieve these goals. We are currently working on an external program that is available on our website. We are registered with ECOVADIS, currently achieving Bronze Status.

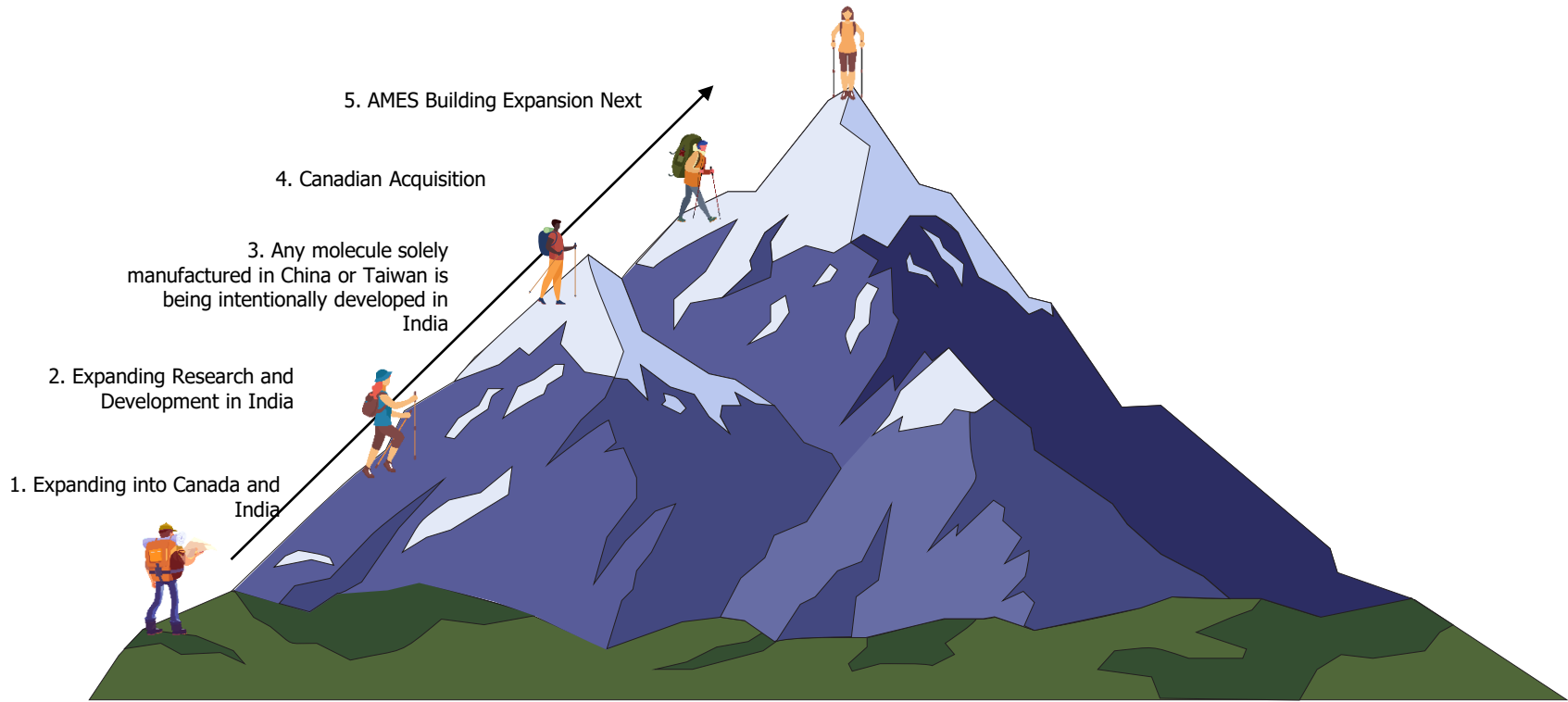


Supply Chain Security

BioSpectra is fundamentally committed to the ideals of Supply Chain Security. We prosecute an aggressive raw material supplier qualification program. Our Quality Program is posted and available on our website. We take very seriously the global supply-chain situation assessing and reacting to threats with real solutions. BioSpectra Inc, continues it's long history of sourcing and qualifying raw material so as not to be sole sourced on any key chemical that originates from only one country.

With Great Growth, Comes Great Responsibility to Increase Our Security of Supply of Raw Materials

It is an Uphill Climb



Strategic Initiatives

Organizational Excellence

Business Continuity Plan	Dora Meissner- Executive Vice President of Quality Systems
Succession Plan	Rick Mutchler- President
100% Validated and Implemented ERP/MRP	Dora Meissner- Executive Vice President of Quality Systems
Human Development Plan	Renee Sommo – Senior Director of Human Development

Quality Excellence

100% Validated and Implemented QMS	Dora Meissner- Executive Vice President of Quality Systems
100% Validated and Implemented LIMS	Amy Yencho- Vice President of Laboratory Services
Expansion of Data Integrity and Quality Programs	Dora Meissner- Executive Vice President of Quality Systems
Buildout of New Laboratory	Amy Yencho- Vice President of Laboratory Services

Manufacturing Excellence

100% Validated and Implemented EBR'S	Peter Underwood- Senior Director of Information Systems
30 Days Critical Product Inventory	Eric Gentile- Vice President of Manufacturing Operations
100% Qualified Equipment and Validated Systems	Dora Meissner- Executive Vice President of Quality Systems
Spray Drying Technology Expansion	TBD

Operational Excellence

100% Sustainable Renewed Buildings	Rick Mutchler- President
100% of Workspace will be Compliant to our Four Levels of Classification	Rick Mutchler- President
100% Uniform and Standardized Workspaces, Break Areas and Offices	Rick Mutchler- President
Property Beautification at Every Facility Completed	Rick Mutchler- President

Environment Excellence

Dust Collection/Cyclone Upgrade Program	Rick Mutchler- President
Commercial Recycling Program Implemented	Rick Mutchler- President
Solid Waste Reduction Program Implemented	Rick Mutchler- President
Liquid Waste Reduction Program Implemented	Rick Mutchler- President

Sustainability Excellence

Vertically Integrated HCl Gas/Liquid Supply	Rick Mutchler- President
100% Energy-Efficient HVAC Systems	TBD
Unified and Expandable Utilities at Each Site	Rick Mutchler- President
Inter-Site Supply Chain Management	Garret Agee- Vice President of Supply Chain

This Strategic Plan will be based on our expectations and goals for our **thirtieth anniversary** and **define primary measurables for the 32-month period starting February 1, 2023 and ending September 30, 2025**

Strategic Initiatives- A Deeper Look

Quality Excellence	<ul style="list-style-type: none">• Maintaining an unblemished Record with the FDA
Manufacturing Excellence	<ul style="list-style-type: none">• Commitment to safety first / Safe Systems / Reduction in Safety Incidents
Environmental Excellence	<ul style="list-style-type: none">• Lowering Energy Consumption per kilo• Carbon Reduction• Reduction in emissions• Increased in renewable energy use• Water Purification Systems
Sustainability Excellence	<ul style="list-style-type: none">• Sustainable Procurement (alternative Sourcing)• Supply Chain Security (New GMP Warehouses)• Financial Stability & Cost Reductions OOS Product• Supply Base Auditing – Quality practices; Environmental Practices; and Social/HR Practices
Corporate Commitment to Social Responsibility	<ul style="list-style-type: none">• Diversity Hiring Program• Community Outreach programs

Additional Organizational commitments

Ethical Commitments

- To follow all US and International Commerce Laws
- To sell only to ethical pharmaceutical companies, affiliates & CMO's
- To Financial Ethics and Accountability
- To Internationally recognized ethical business practices
- To work with only suppliers that provide for basic human rights

Human Development Commitments

- To maintain a happy, healthy and safe work environment
- To increasing efficiency and means of internal Communication
- To advancement in careers, training and education
- To a socially responsible work environment
- To personal growth and improvement through metrics, KPI's and evaluations

Customer Commitment

- To the highest level of customer care
- To the highest level of customer service
- To the highest level of consistent quality of response
- To product continuity (quality) and sustainability
- To customer health and safety

Additionally, BioSpectra is...

