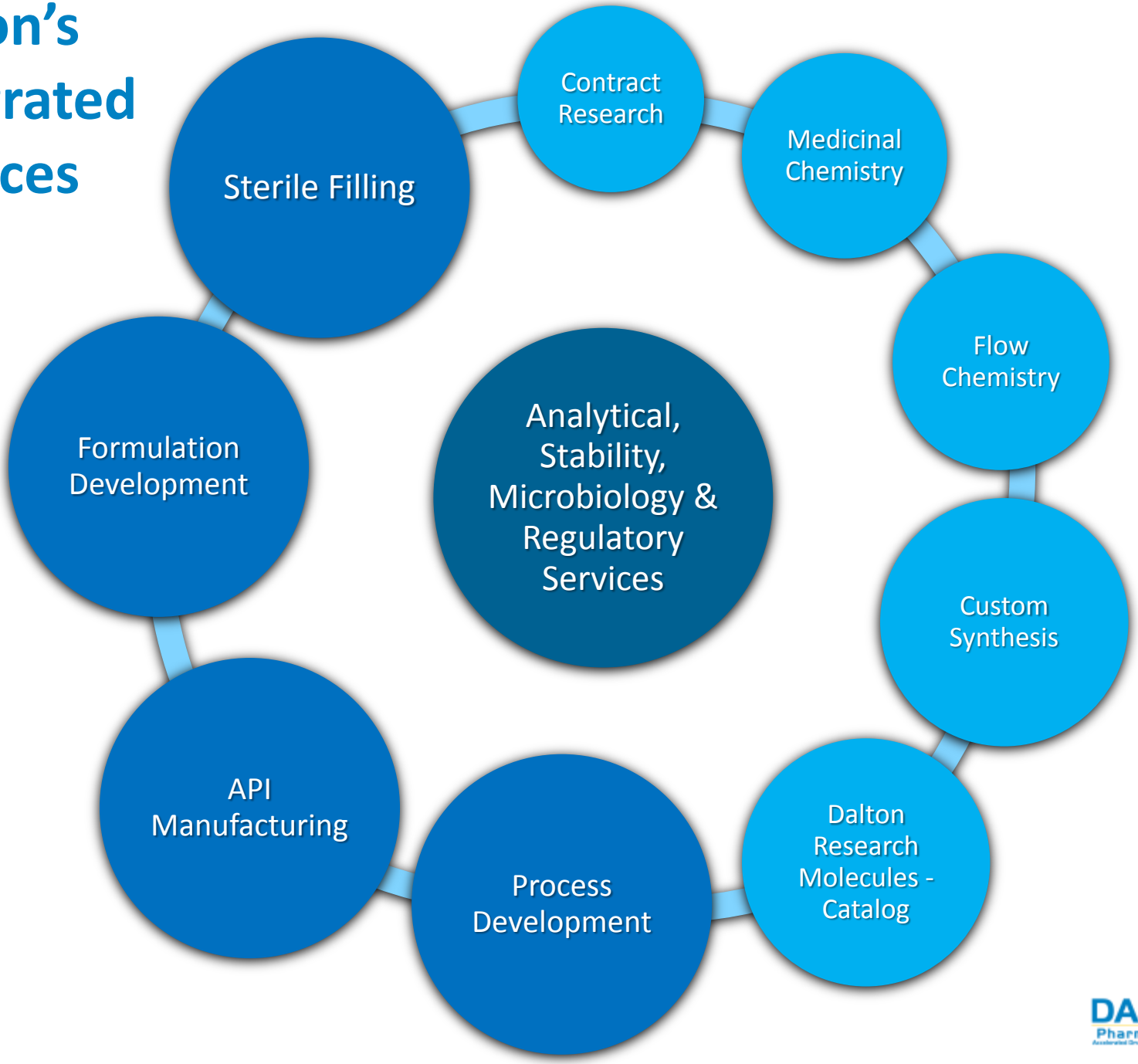
DALTON Pharma Services

Overview Presentation 2016

Integrated Drug Discovery, Development and Manufacturing


Dalton is a CMO with an integrated drug development and manufacturing process that accelerates projects to market while saving our clients time and money.

Dalton's Integrated Services



DALTON Pharma Services

Our Facility

- Secure controlled environment
- Health Canada inspected, EU/FDA standards
- Controlled Drug License
- Fully Integrated services offered at one central location

DALTON
Pharma Services

Integrated Drug Discovery, Development & Manufacturing

Accelerate your product to market.

- Quality, speed and flexibility
- Customized drug development by phase
- Agility to respond quickly and adapt to project changes
- The right size CMO for the right fit - provide continuity and capital efficiency
- CMO 2016 Leadership in 5 categories: Quality, Reliability, Expertise, Capabilities & Compatibility

CMO LEADERSHIP AWARDS 2016

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CHEMISTRY SERVICES

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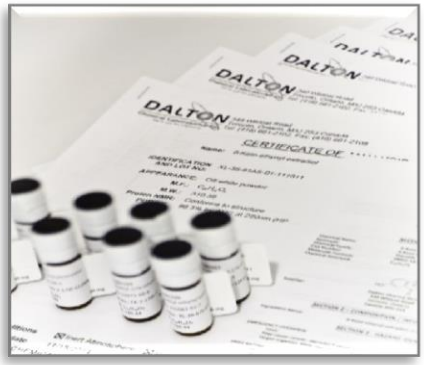
Pharma Services
Accelerated Drug Discovery And Development

Dalton Research Molecules – Catalog

- **Easy access to over 2,000 high quality research molecules many of which are exclusive to Dalton.**
- **Extensive expertise across a wide range of structural classes**
- **CofA and extended analytical testing available.**



- Building blocks
- Coelenterazines
- Nucleic Acids
- Glitazones
- Peptides
- Heterocycles
- Labelled compounds
- Steroids
- Natural Compounds
- Drug and Metabolites
- Organometallics
- Controlled drugs
- Metabolites and Impurities
- GMP APIs, Excipients and Reagents

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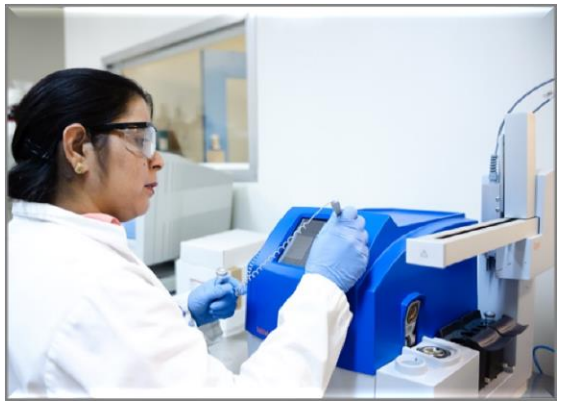
Contract Chemistry Services

Dalton extends your resource base to accelerate your project

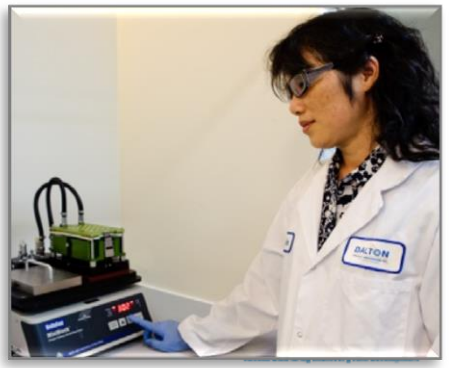
- Process Optimization
- Route Development
- Scale-up
- Synthetic Feasibility
- Legal Case / Expert Witness



Medicinal Chemistry Services

We serve as an extension of your R&D groups

- Design, synthesis and evaluation of new compounds
- Hit-to-lead to identify NCEs for your pipeline
- Drug optimization services
- Computational design modeling support



Custom Synthesis

A specialty since the inception of Dalton.

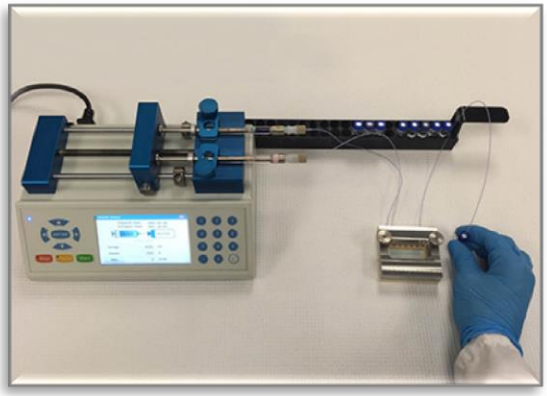
Bench to kg scales

- One-off chemical synthesis at different scales
- Reference Std & Impurity Std synthesis
- Specialty Reagents for Biotechnology
- Full analytical results and CofA

Flow Chemistry

A more cost-effective, efficient and safer approach.

- Increased scalability
- More flexibility
- Easier process control



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Process Development

We have the expertise to optimize your manufacturing process and smoothly transfer your process into GMP.

- mg to multi-kilogram scales (up to 100 L reactors)
- Existing routes optimized or GMP friendly alternative synthesis schemes
- Develop IP protected synthetic routes
- Chiral chemistry applications
- Enantiomer separations
- Kg scale asymmetric transformations
- Troubleshooting

Dalton can apply **Statistical DoE** approaches to some programs.

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Formulation Development Overview

We can accelerate development of your finished dosage form by integrating with your API and/or dose manufacturing programs.

- We offer integrated formulation development services for in-house and external API sources.
  - **Sterile** and **Non-Sterile** formulations
  - Simple and **complex** dosage forms
  - Novel formulations for new/existing products
  - Controlled or sustained release formulation

- Development services offered:
  - Feasibility Studies
  - Excipient Compatibility
  - Product/Process Optimization
  - Process Scale-Up & Technology Transfers

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GMP MANUFACTURING

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cGMP API Manufacturing

Health Canada approved and FDA registered site for manufacturing, packaging and testing of sterile and non-sterile API.

- Gram to multi-kilogram API scales
- Small molecules, peptides and polymers
- Three modern cGMP API manufacturing suites
- Strict environmental monitoring & regulatory support
- **Customer IP rights** clearly defined

FDA REGISTERED FACILITY

Health Products and Food Branch Inspectorate
Inspectorat de la Direction générale des produits de santé et des aliments

Establishment Licence
Licence d'établissement

Health Canada Santé Canada
Canada

DALTON Pharma Services

Sterile and Non-Sterile Filling

Shorten the time and lower the cost of drug development and manufacturing with our fully integrated solutions.

- Dalton offers aseptic filling and terminally sterilized products in a variety of finished dosage forms.

- Liquid fill
- Powder fill
- Aseptic processing
- Sterilization

FDA REGISTERED FACILITY

Health Products and Food Branch Inspectorate / Inspectorat de la Direction générale des produits de santé et des aliments
Establishment Licence
Licence d'établissement
Health Canada Santé Canada Canada

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ANALYTICAL SERVICES

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Analytical & Stability Services

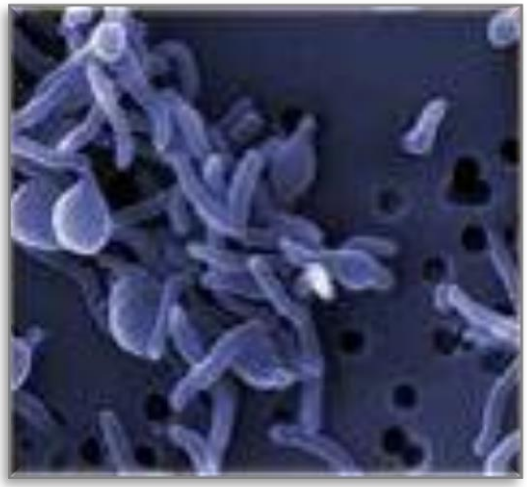
We provide uninterrupted project support saving you time & money.

- Research, Analytical Development, Release Testing
- Stability Services
  - Meet ICH guidelines for drug substance & drug product
  - Protocol development, accelerated, intermediate & long term programs
  - Data & trend analysis and stability reports
- Modern instrumentation
- Quality you can trust
- Regulatory requirements (including CMC)

Microbiology

Ensure your sterile product success.

- Bioburden Analysis
- Environmental Monitoring
- Water Testing
- Bacterial Endotoxin Testing
- Particulate Matter
- Bacterial Retention Validation
- Sterility Assurance



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Our Focus

- Dalton provides integrated services to support the **discovery**, **development** and **manufacturing** of pharmaceutical and biotechnology products.
  - Pre-clinical
  - Phase I
  - Phase II
  - Phase III
  - Small Scale Commercial

- We bring 30 years of experience to our client's projects and emphasize quality, speed and flexibility.

- We reduce your timelines and costs and accelerate your product to market through our **Integrated Drug Discovery, Development and Manufacturing process.**

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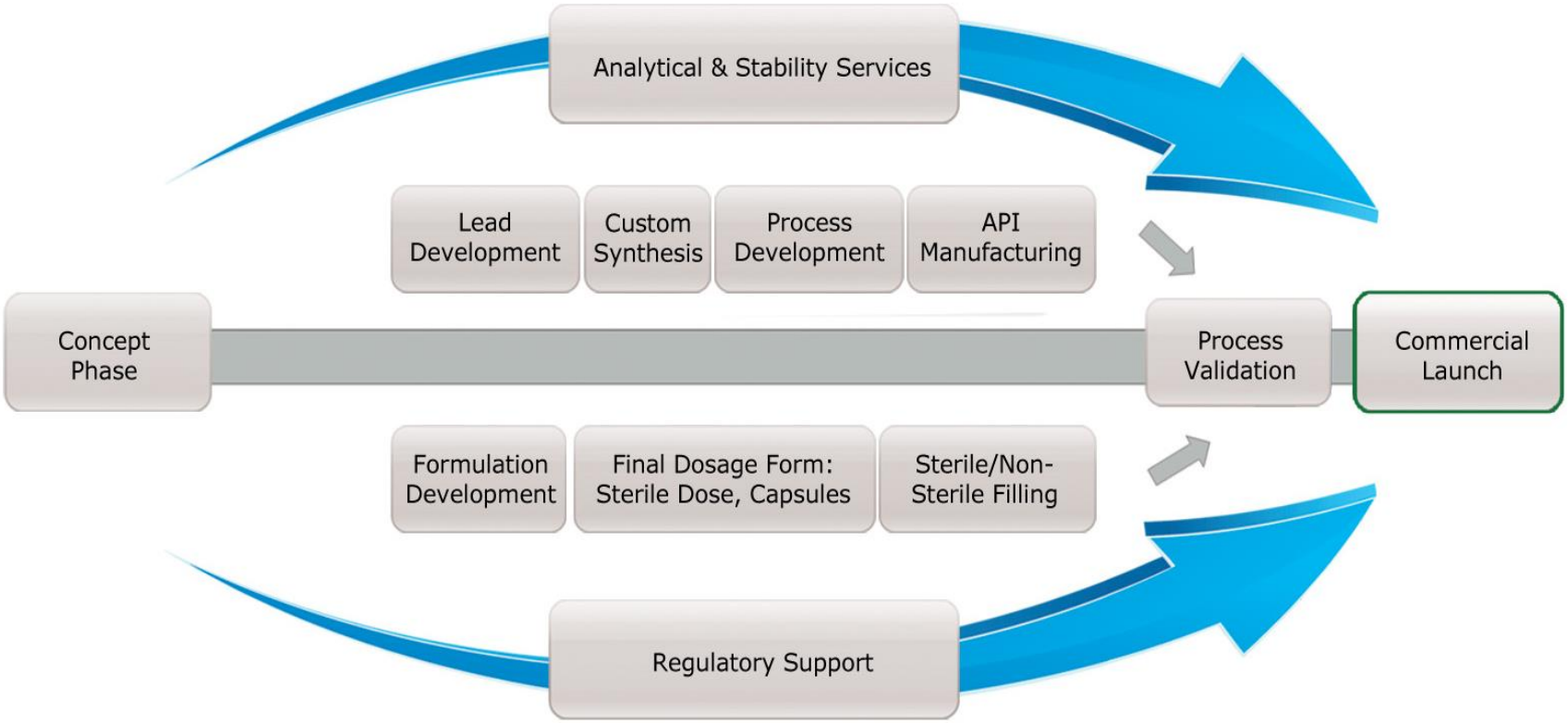
Integrated Drug Discovery, Development and Manufacturing

Reduce timelines and costs through all phases of development and manufacturing - *accelerate your product to market.*



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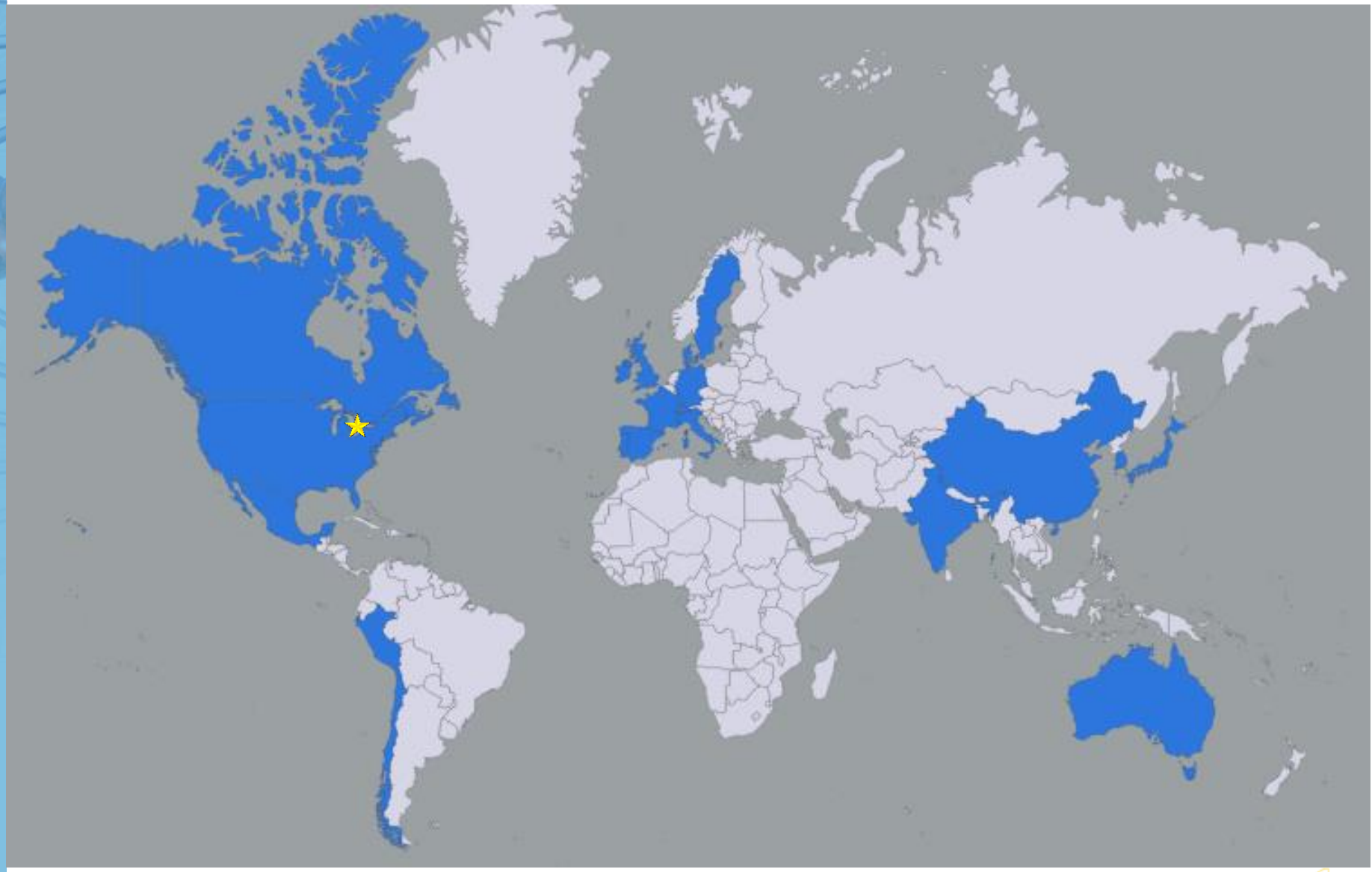
Dalton Serves Global Markets



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Accelerated Drug Discovery And Development

Our Customers

"Our success is measured by the quality of our relationships"

Boehringer Ingelheim

UNIVERSITY of GUELPH

ThermoFisher SCIENTIFIC

novo nordisk®

AstraZeneca

Zafgen

Dedicated to the treatment of obesity.

ONCOVIR®

DEFENCE R&D DÉFENSE

EyeGate pharma

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For more information please visit our website
www.dalton.com

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