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.
Our Facility

- Secure controlled environment
- Health Canada inspected, EU/FDA standards
- Controlled Drug License
- Fully Integrated services offered at one central location
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
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
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
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.
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
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
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
ANALYTICAL SERVICES
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
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**.
Integrated Drug Discovery, Development and Manufacturing

Reduce timelines and costs through all phases of development and manufacturing - *accelerate your product to market.*
Dalton Serves Global Markets
Our Customers

“Our success is measured by the quality of our relationships”

Dedicated to the treatment of obesity.