



# APL - your partner in drug product manufacturing

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# Our vision



“To be the most attractive partner and workplace for development and manufacturing of specials and pharmaceuticals”



# APL offers products and services in three business areas



**Health care**

**Pharmacies**



**Life science**



# APL produces special pharmaceuticals to the Swedish health care



- A special pharmaceutical is a drug which is not commercially available by the pharmaceutical industry, but for which there is a medical need.
- 1-2 % of the drugs prescribed in Sweden
- APL manufactures special pharmaceutical as Individual or batch manufactured extemporaneous

# APL supports the pharmacies with products and services



- Development and manufacturing of pharmaceutical products
- Quality review of products
- Dose dispensing aids

# APL offers CDMO services that cover the entire development chain.



Pre-clinical  
development

Clinical  
development

Commercial  
manufacturing

Pre formulation development

Formulation development

Tech transfer

Analytical method development

Manufacturing of CTM

Scale up

Commercial manufacturing    QA release

Stability studies

Packaging and labeling

Packaging and labeling

Randomization

Stability studies

CMC documentation



# Flexible and efficient manufacturing for clinical trials and commercial use

## Aseptic/Sterile

- Parenteral preparations
  - Vials
  - Bottles
  - Ampoules
- Eye/Ear preparations
  - Drops
  - Ointments
  - Gels
- Ambulatory systems
  - Infusion bags

## Non sterile

- Semi-solids
  - Creams
  - Gels
  - Lotions
  - Ointments
- Liquids
  - Oral solutions
  - Emulsions
  - Suspensions
- Solid preparations
  - Capsules

# Small and flexible organisation and manufacturing suits



# Focus on pediatrics



# APL has all its manufacturing sites in Sweden



**Göteborg**



**Umeå**



**Malmö**



**Stockholm**



# Quality Assurance

- Full cGMP compliant manufacturing
- A QA system covering all activities in the development process
- Regularly inspected by EMA, FDA
  - EMA every third year
  - FDA 2001/2005/2010
- Over 30 client audits annually



# Sustainable Development



- A management system certified and in compliance with
  - ISO 14001 (environment) and
  - OHSAS 18001(occupational health and safety)
- Committee of Sustainability available at all sites
- LEAN Green – Increased customer value by reducing waste of resources

# APL in brief



- Annual turnover of over 500 MSEK
- Four modern manufacturing units in Sweden
- More than 200 clients, both global big pharma and biotech's
- Drug Product manufacturing covering both aseptic/sterile and non-sterile products

# Thank you!



[www.apl.se](http://www.apl.se)