

QPharma: specialists in the development and manufacture of controlled-release polymeric devices

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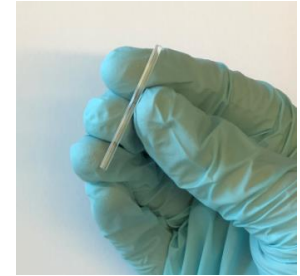
Who we are

- Specialty CDMO
- Established in 1975
- Mid-sized, 180 employees
- Located in Malmö, Sweden
- Privately owned company



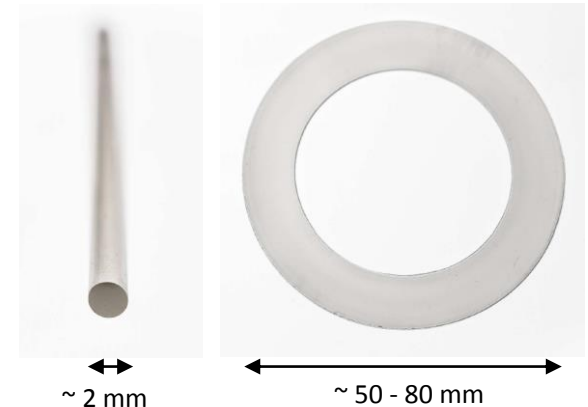
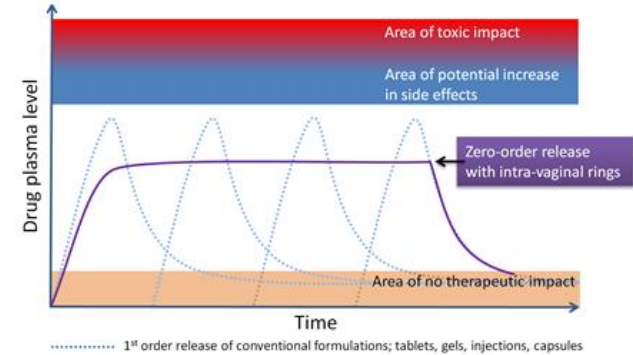
What we do

- **Our core business:**
 - Design, develop and manufacture **polymeric dosage forms**
 - **Types:** vaginal rings, implants, intra-uterine systems
 - **Materials:** silicone, EVA, hydrophilic PU
 - **Purpose:** controlled release of API(s)
 - **Indications:** long term/chronic conditions, e.g. reproductive health, contraception, HIV prevention
 - Manufacture of pharmaceuticals containing **highly active drugs**
 - E.g. contraceptive steroids
 - Manufacture solid dosage forms



Advantages of polymeric dosage forms

- Longer acting products
 - Infrequent need for removal or replacement
 - Improved patient compliance and convenience
- Controlled delivery of API(s)
 - Improved pharmacokinetic profile, potentially allowing lower dosing and reduction of side effects
- Individually tailored simultaneous delivery of multiple APIs
- Business considerations:
 - Life cycle management
 - Higher generic entry threshold resulting from technological and clinical (BE) complexity
 - New patents potentially could further contribute to exclusivity



How we do it

1. Our core technologies:

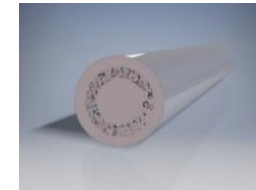
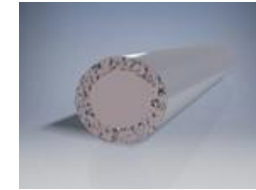
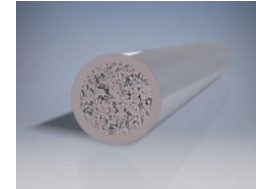
- Co-extrusion
 - Manufacture of reservoir and layered drug releasing systems
- Injection molding
 - Manufacture of vaginal rings and implants
- Joining techniques
 - E.g. polymer welding
- Containment systems
 - For products containing highly active APIs



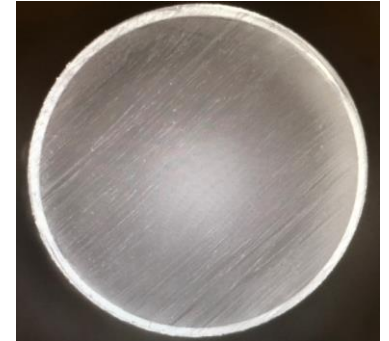
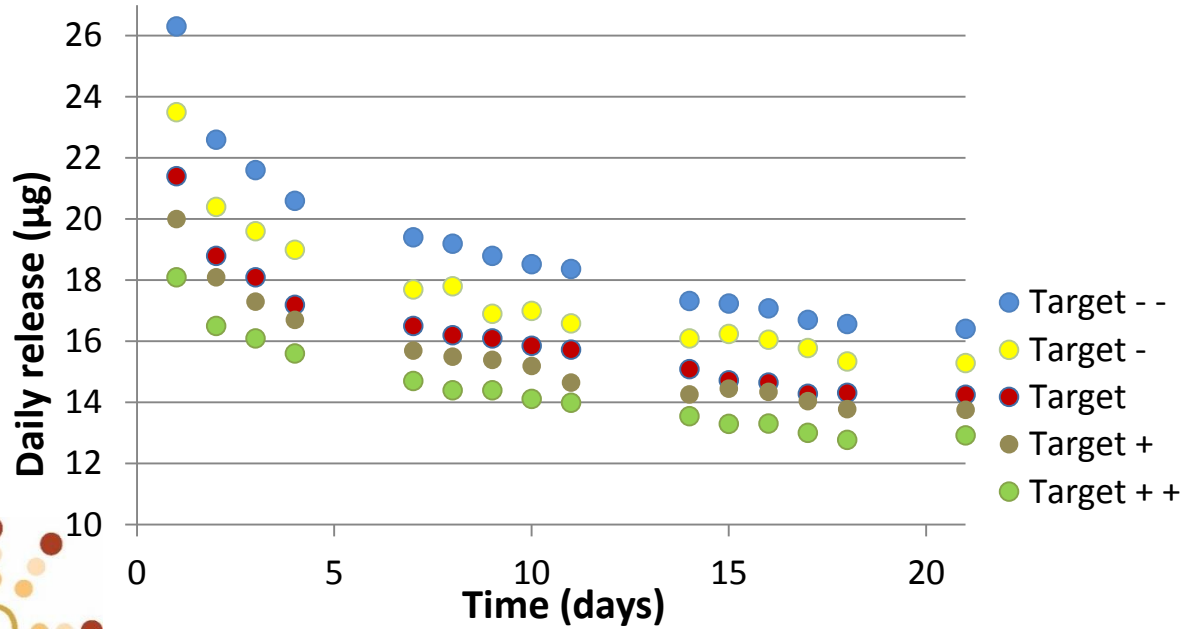
Layered designs

A versatile drug delivery technology

- **Reservoir system**
 - Drug embedded in the matrix
 - No dose dumping
 - Near zero-order release
- **Drug-loaded outer layer**
 - Release similar to a matrix system
 - Reduced residual drug content
- **Multi-layered systems**
 - Versatile system for independent release of two or more drugs
 - Stable at room temperature



Influence of membrane thickness



How we do it

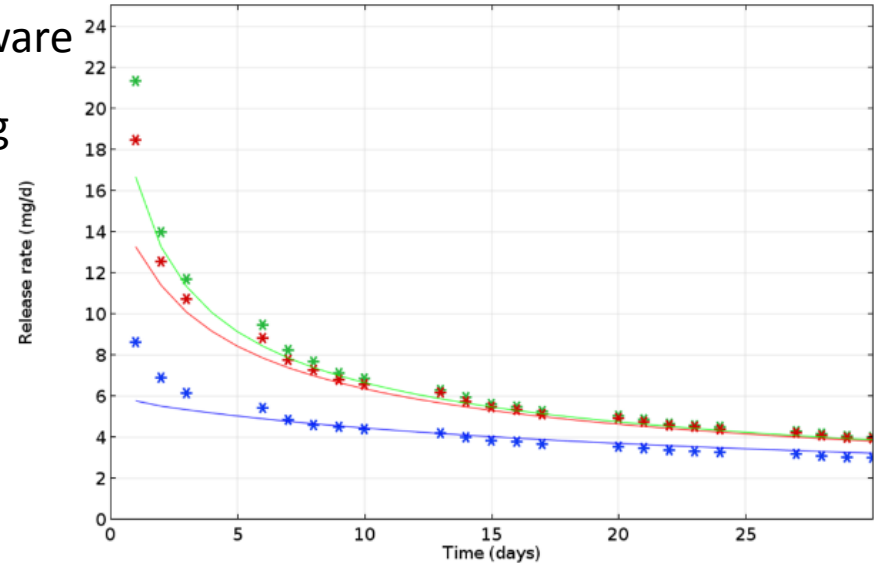
2. Our expertise in development:

- Focus on our core technologies
- Conceptual design of polymeric dosage forms
 - E.g. using computational modelling, QbD
- Quality (GMP) and regulatory aspects related to drug-device combination products
- Understanding of the overall drug development process
- Conscious of challenges posed by up-scaling



Computational modelling

- FE-modelling using advanced software
- Near quantitative predictions using model accounting for dissolving particles
- Requires determination of basic parameters (D and C_s) only



How we do it

3. Our expertise in manufacture

- Most experienced CDMO in vaginal ring technology
 - Commercial manufacturing of two approved rings
 - Estring® (Pfizer)
 - Annovera™ (TherapeuticsMD)
- Working on multiple ring and implant concepts in various stages of development
- Commercial partner
 - Industrial focus
 - Automation



FDA Approves the First One-Year Contraceptive Fully under a Woman's Control



New Population Council-Developed Product Expands Family Planning Options

NEWS PROVIDED BY
[Population Council](#) →
Aug 10, 2018, 15:22 ET

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Why us?

- **Core technologies**
 - Focussed on polymer-based dosage forms
 - Ability to work with highly active substances
 - Industrial focus
 - Product should be produced in large numbers in a cost efficient way
- **Expertise**
 - Development of new and generic products
 - Commercial manufacture
- **Quality**
 - Excellent track record of regulatory inspections
 - E.g. FDA pre-approval inspection



Acknowledgements

- Pia Jönsson
 - Project Director
- Wouter de Graaff
 - Director Strategy & Technology
- The extended team at QPharma



Thank you!

- Visit us at our booth for further information

