ROMMELAG
CDMO

# ROMMELAG CDMO
# CAPABILITIES

| PRODUCT CHARACTERISTSICS | | BATCH SIZE | PRIMARY PACKAGING/FILLING |
|---|---|---|---|
| **AQUEOUS** | ◁ Sterile / non-sterile products <br> ◁ Foamy products | ◁ Up to 20,000 l depending on fill volume and product characteristics <br> ◁ Bulk autoclaving within tank possible up to 3,000 l <br> ◁ Batch sizes only limited through tank dimensions. Multiple tank connections possible <br> ◁ (Sterile) Filtration or aseptic filling only | ◁ 0.04 ml – 1,200 ml with LDPE <br> ◁ A more limited range with HDPE (principally 5 ml – 1,000 ml possible) and PP (5 ml – 500 ml) <br> ◁ Coloured polymers and resin blends (typically HDPE / LDPE) possible <br> ◁ Filling under nitrogen possible <br> ◁ Terminal sterilization possible <br> ◁ Microdosing and defined drop size possibilities <br> ◁ Multidose capabilities <br> ◁ Insert technology for stopper, cap, dropper, brush or similar insertion directly in the BFS process available |
| **OILY** | ◁ Sterile / non-sterile products | ◁ Usually up to 3,000 l – larger sizes to be discussed | |
| **EMULSIONS** | ◁ Sterile / non-sterile products | ◁ With homogenization (high shear) 90 l – 1,200 l <br> ◁ Bulk autoclaving within tank possible <br> ◁ High pressure homogenisation (typical for micro-emulsions) not available | |
| **SUSPENSIONS** | ◁ Sterile / non-sterile products <br> ◁ Recirculation available | ◁ 90 l – 1,200 l with homogenization (high shear) <br> ◁ Bulk autoclaving within tank possible <br> ◁ Use of sterile API currently possible up to 500 l | |
| **GELS/FLUENT VISCOUS** | ◁ Sterile / non-sterile products <br> ◁ Viscosity up to 150,000 cps | ◁ 90 l – 1,200 l with homogenization (high shear) <br> ◁ Bulk autoclaving within tank possible <br> ◁ Use of sterile API currently possible up to 500 l <br> ◁ Product must be fluent for filling | ◁ Up to 100 ml <br> ◁ With HDPE and PP a more limited range <br> ◁ Coloured polymers and resin (typically HDPE/LDPE) blends possible <br> ◁ Terminal sterilization possible <br> ◁ Speciality are vaginal and rectal applicators |

# CDMO SERVICES

→ Analytical method validation / transfer / verification

→ Support for:
  · Development
  · Laboratory scale batches
  · Functional hand-filled ampoules
  · Scale-up batches
  · Pilot batches
  · Optimization of formulations
  · Risk assessments
  · Validation (cleaning, filter, process, microbiological, Autoclave)
  · Stability studies

→ Inhouse BFS-container development/ 3D prints

→ Extractables study for primary resins

→ Stability and registration batches

→ Clinical batches

→ Regulartory support for registration dossiers

→ Full scale commercial batches

→ BFS Test Kit

→ Partner Laboratories for:
  · Analytical method development
  · Leachables

## SPECIAL PRODUCT GROUPS

### BIOLOGICALS
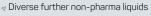- Proteins / Peptides (synthetic and recombinant)
- Mono- and polyclonal antibodies, DNA, RNA
- Cytokines
- Vaccines, incl. "live" viruses and genetically modified organisms up to Bio Safety Level 2

### NARCOTICS
- Sedatives, Anesthetics, Anti-Convulsiva

### BLOOD PRODUCTS
- Plasma constituents

### IMMUNO-SUPPRESSANT
- Glucocorticoids, Receptor Antagonists

### HORMONES
- Diverse hormones

### ANTIBIOTICS
- Diverse, except ß-lactam Antibiotics

### PHYTOPHARMA-CEUTICALS
- Diverse plant extracts

### HOMEOPATHIC DRUGS
- Diverse, incl. potentiation

### VET. MED. DRUGS
- Diverse but with ANVISA restrictions

### DIETARY SUPPLEMENTS
- Sterile / non-sterile products

### COSMETICS
- Sterile / non-sterile products

### TECHNICAL PRODUCTS
- Motor Oils
- Detergents and Cleaning Agents
- Pheromones and similar products
- Chemicals
- Fertilizers and further agricultural products
- Aquaristic products
- Diverse further non-pharma liquids

Apart from the product groups listed above, standard products such as eye and ear drops (single as well as multi-use) the latter including non-preserved products, rinsing solutions, parenterals, orals, etc. with fill volumes between 40μl and 1200ml can be manufactured.

*Please note that we do not have any own products or product registrations and thus cannot offer manufacture of private label products.*

## SECONDARY PACKAGING

### FOR ALL ITEMS excl. TECHNICAL PRODUCTS
- Embossing of data on containers
- Container labelling
- Shrink sleeves
- Pouching in aluminium or other foil, also with nitrogen
- Packaging in cardboard boxes with leaflets / inserts
- (Bulk) Packaging in shipper cartons or any other shipper
- Ink jetting of pouches and cardboard boxes
- Serialization / Aggregation
- UDI

### FOR TECHNICAL PRODUCTS
- Container labelling
- Limited pouching in aluminium foil
- Packaging in cardboard boxes with leaflets / inserts
- (Bulk) Packaging in shipper cartons
- Serialization / Aggregation

## QUALITY CONTROL
- General chemical and physical testing
- ID and analytic assays (compendial or transferred methods)
- Bioburden
- Sterility
- Further testing procedures (e.g. molecular biological methods, method development and validation) possible
- Microbial Identification
- Endotoxins

## ADDITIONAL GENERAL SERVICES
- Cold storage
- Market release