

ROMMELAG CDMO

CAPABILITIES

PRODUCT RANGE



DRUGS & MEDICAL DEVICES incl. BIOLOGICALS

NARCOTICS

IMMUNO-SUPPRESSANT

ANTIBIOTICS

PHYTOPHARMACEUTICALS

HOMEOPATHIC DRUGS

VET. MED. DRUGS

- ▽ Proteins / Peptides (synthetic and recombinant)
- ▽ Recombinant products (e.g. mono- and polyclonal antibodies, DNA, RNA)
- ▽ Hormones
- ▽ Prostaglandins
- ▽ Cytokines
- ▽ Blood products (no whole blood)
- ▽ Vaccines, "live" virus vaccines, genetically modified organisms up to Bio Safety Level 2
- ▽ Narcotics with PDE > 10 µg / kg
- ▽ Narcotics with PDE < 10 µg / kg with dedicated equipment / special precautions

BATCH SIZE

- ▽ Batch sizes dependent on requirements such as cooling and nitrogen overlays

PRIMARY PACKAGING/FILLING

- ▽ 0.1 ml – 1,200 ml with LDPE
- ▽ A more limited range with HDPE (principally 5 ml – 1000 ml possible) and PP (5 ml – 500 ml)
- ▽ Coloured polymers and resin blends (typically HDPE/LDPE) possible
- ▽ Filling of temperature sensitive products possible
- ▽ Filling under nitrogen possible
- ▽ Application of "cool-BFS" for very temperature sensitive products
- ▽ Continuous cooling, filling the product at temperatures not more than 25 – 30 °C
- ▽ Minimal product losses



DIETARY SUPPLEMENTS



COSMETICS



TECHNICAL PRODUCTS

- ▽ Motor oils
- ▽ Detergents
- ▽ Pheromones and similar products
- ▽ Chemicals
- ▽ Pesticides, herbicides and fungicides (agricultural use)
- ▽ Desinfection solutions
- ▽ Fertilizers
- ▽ Aquaristics

- ▽ Separate fillig facility
- ▽ Batch sizes principally not limited
- ▽ Bulk product must be provided

- ▽ 0.25 ml – 1000 ml
- ▽ With HDPE a more limited range
- ▽ Coloured polymers and resin blends (typically HDPE/LDPE) possible
- ▽ PP not possible
- ▽ Terminal sterilization not possible



GROUP-A AQUEOUS

- ▽ Sterile / non-sterile products
- ▽ Foamy products
- ▽ Highly alcoholics (up to 70%)



GROUP-B OILY

- ▽ Sterile / non-sterile products



GROUP-C GELS/FLUENT VISCIOUS

- ▽ Sterile / non-sterile products
- ▽ Viscosity up to 150,000 cps



GROUP-D SUSPENSIONS

- ▽ Sterile / non-sterile products
- ▽ Recirculation to be implemented



GROUP-E EMULSIONS

- ▽ Sterile / non-sterile 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
- ✦ Ink jetting of pouches and cardboard boxes
- ✦ Serialization / Aggregation
- ✦ UDI
- ✦ No direct ink jetting on containers

FOR TECHNICAL PRODUCTS

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

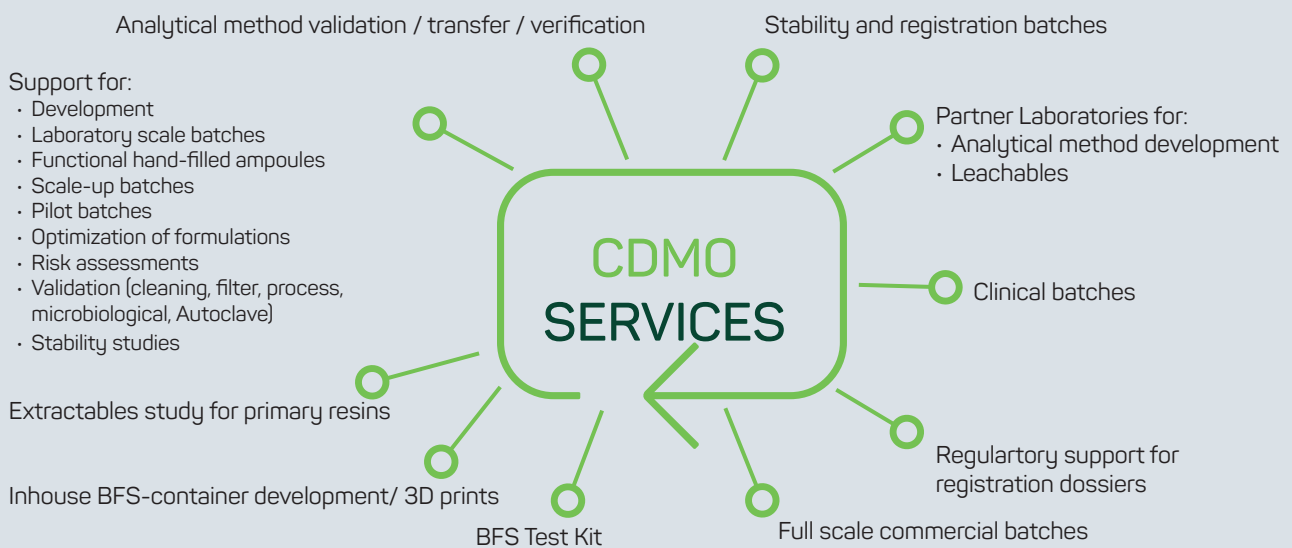
QUALITY CONTROL

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

ADDITIONAL GENERAL SERVICES

- ✦ Cold storage
- ✦ Market release

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



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