






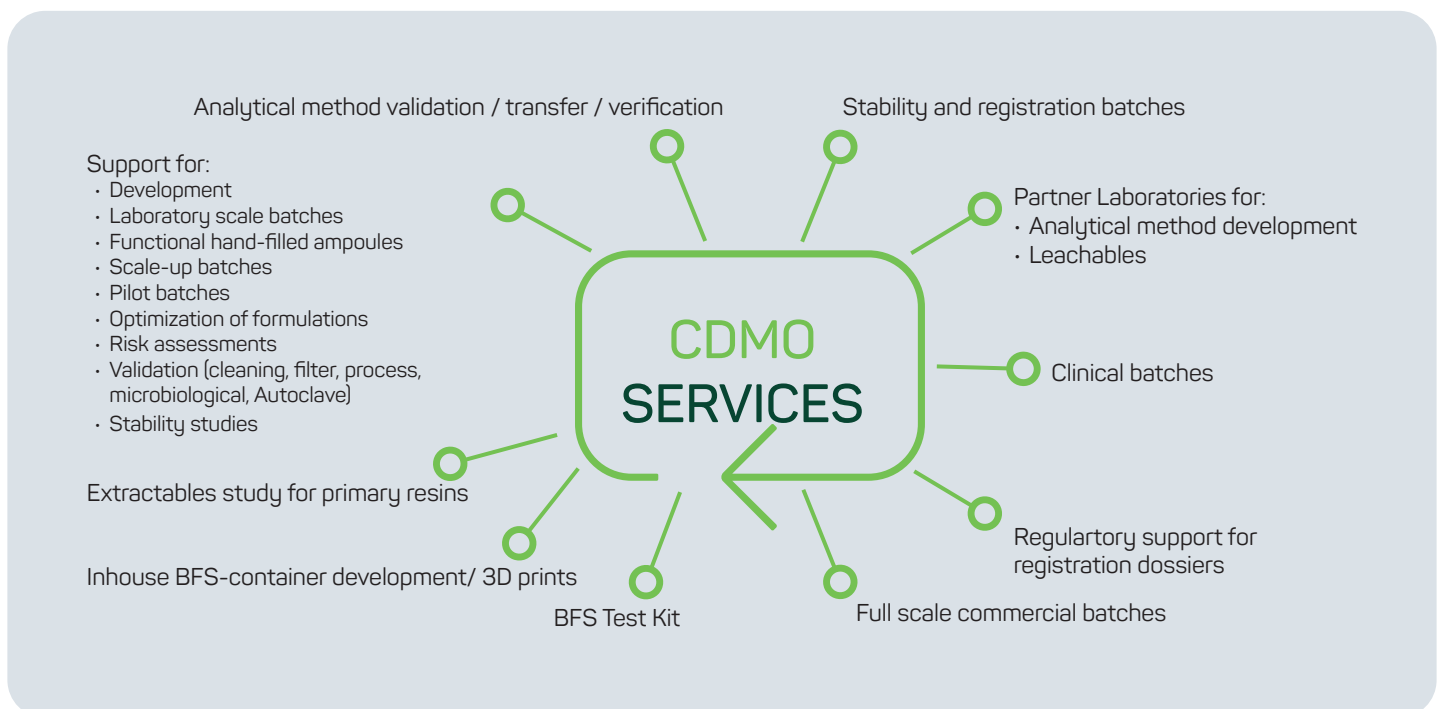
FILLING YOUR NEEDS







ROMMELAG CDMO CAPABILITIES



PRODUCT CHARACTERISTICS	BATCH SIZE	PRIMARY PACKAGING/FILLING
 AQUEOUS <ul style="list-style-type: none"> Sterile / non-sterile products Foamy products Highly alcoholic products (up to 70 %) 	<ul style="list-style-type: none"> Up to 20,000 l depending on fill volume and product characteristics Bulk autoclaving within tank possible up to 3,000 l Batch sizes only limited through tank dimensions. Multiple tank connections possible (Sterile) Filtration or aseptic filling only 	<ul style="list-style-type: none"> 0.04 ml – 1,200 ml with LDPE A more limited range with HDPE (principally 5 ml – 1,000 ml possible) and PP (5 ml – 500 ml) Coloured polymers and resin blends (typically HDPE / LDPE) possible Filling under nitrogen possible Terminal sterilization possible Microdosing and defined drop size possibilities Multidose capabilities Insert technology for stopper, cap, dropper, brush or similar insertion directly in the BFS process available
 OILY <ul style="list-style-type: none"> Sterile / non-sterile products 	<ul style="list-style-type: none"> Usually up to 3,000 l – larger sizes to be discussed 	
 EMULSIONS <ul style="list-style-type: none"> Sterile / non-sterile products 	<ul style="list-style-type: none"> With homogenization (high shear) 50 l – 1,200 l Bulk autoclaving within tank possible High pressure homogenisation (typical for micro-emulsions) not available 	
 SUSPENSIONS <ul style="list-style-type: none"> Sterile / non-sterile products Recirculation to be implemented 	<ul style="list-style-type: none"> 50 l – 1,200 l with homogenization (high shear) Bulk autoclaving within tank possible Use of sterile API currently possible up to 500 l 	
 GELS/FLUENT VISCIOUS <ul style="list-style-type: none"> Sterile / non-sterile products Viscosity up to 150,000 cps 	<ul style="list-style-type: none"> 50 l – 1,200 l with homogenization (high shear) Bulk autoclaving within tank possible Use of sterile API currently possible up to 500 l Product must be fluent for filling 	



PRODUCT RANGE	BATCH SIZE	PRIMARY PACKAGING/FILLING
 <p>DRUGS & MEDICAL DEVICES incl. BIOLOGICALS</p> <ul style="list-style-type: none"> 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 <p>NARCOTICS</p> <ul style="list-style-type: none"> Narcotics with PDE > 10 µg / kg Narcotics with PDE < 10 µg / kg with dedicated equipment / special precautions <p>IMMUNO-SUPPRESSANT</p> <p>ANTIBIOTICS</p> <p>PHYTOPHARMACEUTICALS</p> <p>HOMEOPATHIC DRUGS</p> <p>VET. MED. DRUGS</p>	<ul style="list-style-type: none"> Batch sizes dependent on requirements such as cooling and nitrogen overlays 	<ul style="list-style-type: none"> 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 Disposable filling options available
 <p>DIETARY SUPPLEMENTS</p>	<ul style="list-style-type: none"> Batch sizes dependent on requirements 	
 <p>COSMETICS</p>	<ul style="list-style-type: none"> Batch sizes dependent on requirements 	
 <p>TECHNICAL PRODUCTS</p> <p>Like for example:</p> <ul style="list-style-type: none"> Motor oils Detergents Pheromones and similar products Chemicals Pesticides, herbicides and fungicides (agricultural use) Desinfection solutions Fertilizers Aquaristics and further non-sterile liquids 	<ul style="list-style-type: none"> Separate fillig facility Batch sizes dependent on requirements 	<ul style="list-style-type: none"> 0.25 ml – 1000 ml Coloured polymers and resin blends (typically HDPE/LDPE) possible Terminal sterilization not possible Recycled resin can be used

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

SECONDARY PACKAGING	QUALITY CONTROL
<p>FOR ALL ITEMS excl. TECHNICAL PRODUCTS</p> <ul style="list-style-type: none"> 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 <p>FOR TECHNICAL PRODUCTS</p> <ul style="list-style-type: none"> Container labelling Limited pouching in aluminium foil Packaging in cardboard boxes with leaflets / inserts (Bulk) Packaging in shipper cartons Serialization / Aggregation 	<ul style="list-style-type: none"> 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 <p>ADDITIONAL GENERAL SERVICES</p> <ul style="list-style-type: none"> Cold storage Market release

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