


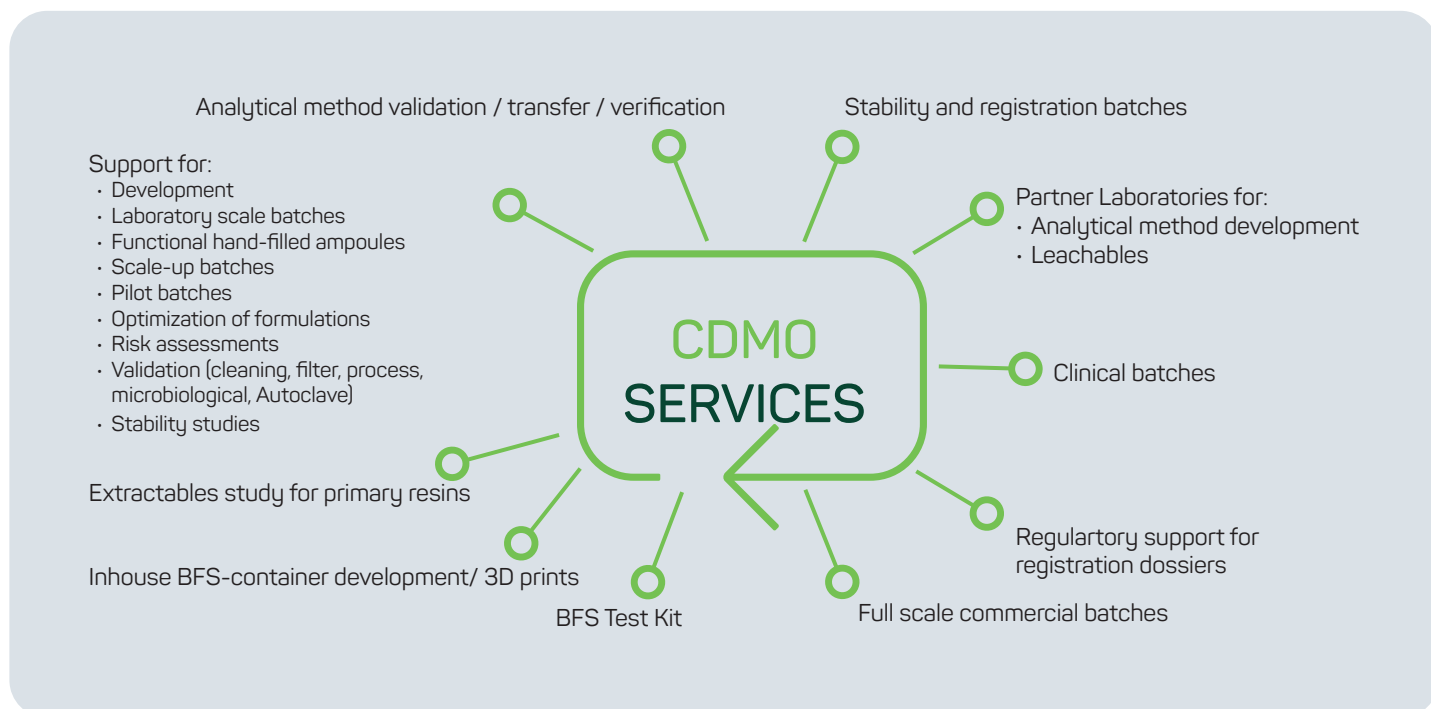
FILLING YOUR NEEDS




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"> ▽ Usually up to 3,000 l – larger sizes to be discussed 	
	EMULSIONS	<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"> ▽ 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"> ▽ 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 	
	<ul style="list-style-type: none"> ▽ Sterile / non-sterile products ▽ Viscosity up to 150,000 cps 	<ul style="list-style-type: none"> ▽ Up to 100 ml ▽ With HDPE and PP a more limited range ▽ Coloured polymers and resin (typically HDPE/LDPE) blends possible ▽ Terminal sterilization possible ▽ Typically 0.5 g – 5 g with LDPE ▽ Speciality are vaginal and rectal applicators 	



PRODUCT RANGE		BATCH SIZE	PRIMARY PACKAGING/FILLING	
 DRUGS & MEDICAL DEVICES incl. BIOLOGICALS NARCOTICS IMMUNO-SUPPRESSANT ANTIBIOTICS PHYTOPHARMA-CEUTICALS HOMEOPATHIC DRUGS VET. MED. DRUGS	<ul style="list-style-type: none">Proteins / Peptides (synthetic and recombinant)Recombinant products (e.g. mono- and polyclonal antibodies, DNA, RNA)HormonesProstaglandinsCytokinesBlood products (no whole blood)Vaccines, "live" virus vaccines, genetically modified organisms up to Bio Safety Level 2Narcotics with PDE > 10 µg / kgNarcotics with PDE < 10 µg / kg with dedicated equipment / special precautions	<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 LDPEA 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) possibleFilling of temperature sensitive products possibleFilling under nitrogen possibleApplication of "cool-BFS" for very temperature sensitive productsContinuous cooling, filling the product at temperatures not more than 25 – 30 °CMinimal product losses	
	DIETARY SUPPLEMENTS			
	COSMETICS			
	TECHNICAL PRODUCTS	<ul style="list-style-type: none">Motor oilsDetergentsPheromones and similar productsChemicalsPesticides, herbicides and fungicides (agricultural use)Desinfection solutionsFertilizersAquaristics		<ul style="list-style-type: none">Separate filling facilityBatch sizes principally not limitedBulk product must be provided

*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
FOR ALL ITEMS excl. TECHNICAL PRODUCTS <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 Ink jetting of pouches and cardboard boxes Serialization / Aggregation UDI No direct ink jetting on containers FOR TECHNICAL PRODUCTS <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 (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 <ul style="list-style-type: none"> Cold storage Market release

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