

COLLIN® Medical and Pharmaceutical Technology



**FDA-compliant lines provide the highest production standard
Full support for qualification and validation according to FDA**

Single-Screw Extruders

Types: ME 16, ME 20, ME 25, ME 30, ME 45

Length of processing unit is 25:1 L/D or 30:1 L/D. Barrier screws are available for 30 mm and 45 mm screw diameters. The barrels are water-cooled as are the asynchronous servo drives. These extruder series cover a wide range of throughputs from 0.05 kg/h to 45 kg/h.

The control system is microprocessor-based with an LCD display as user interface. For fast and safe data access, a data wheel is included. Touch screen is available as an option.

A melt pump can be integrated into the control system.

The ability to adjust the height and angle of the extruder's axis permits easy adjustment and good access for cleaning.



Twin-Screw Compounders

Types: MZK 12, MZK 16, MZK 25, MZK 35

All machines can be changed easily from co-rotating to counter-rotating. For fast and easy cleaning, all barrel elements are designed with a C-clamp and are water-cooled.

The machines cover a wide range of throughputs from 0.05 kg/h to 70 kg/h.

The control system is similar to that of the single-screw extruders.

A melt pump can be integrated in the control system.

High-precision gravimetric dosing systems are available in each configuration.



Catheter Tubes

*Mono- and multilayer tubes
Mono- and multi lumen tubes*



Various types of extruders between ME16 and ME30 provide a throughput range from 0.05 kg/h up to 15 kg/h. The modular design of the line components assures high flexibility in production. The product range consists of coating wires, mono-layer, multilayer, mono-lumen, multi-lumen catheters.



The materials used are polyolefins and polyurethanes, flexible PVC and polyamides. The line covers the diameter range between 0.5 mm

and 5 mm at a maximum line speed of 100 m/min. Diameter-controlled haul-off speed provides tight diameter tolerances.

Infusion Bags

For the production of 3, 5 or 7 layer water cooled blown film for infusions bags and secondary packaging



Vertical extrusion into a water cooling ring provides optimum film transparency. The new spiral distribution die



provides accurate thickness distribution. The maximum lay-flat width is 530 mm. Throughput is up to 100 kg/h.

All modular components such as extruders, coextrusion dies, haul-off, winders and data acquisition are fine tuned for perfect operation.

Pills Forming

Calenders for continuous production of drug loaded polymers



Calender Types: PK 110 and PK 200

These machines are based on the COLLIN® measuring roll mills, which are well-established in the R&D departments of polymer material producers around the world for more than thirty years. Rigid machine construction and true-running rolls provide the basis for maximum machine accuracy.

The calenders are designed for nip forces up to 10 t. Automatic nip width adjustment and nip width control ensure precisely formed pills. Nip forces and torques are measured and reported for quality assurance. When combined with a compounder from the MZK series, melt pump, flat film die and cooling belt, a complete

pill production line can be established. A touch screen system controls the process and gives a wide range of parameters for filing, evaluation and reporting.

Pelletizing Lines

For the production of Pellets of drug loaded polymers for further extrusion and injection moulding.

The **MZK 16**, **MZK 25** and **MZK 35** compounders can be converted into production pelletizing lines when combined with a melt pump, strand die, cooling belt and pelletizer.

Mono-, dual- and triple-strand dies are available.

High-precision gravimetric dosing stations ensure a dosing accuracy of $\pm 1\%$. The throughput range is from 0.15 kg/h to 70 kg/h.

Different types of cooling belts provide the best cooling capacity for each throughput and strand type.

Available belt cooling:

- Natural convection and roll systems for compact extension of the cooling length.
- Additional air cooling directly on the strand combined with recooling of the belt by cold water.



High-Precision Strands

For the production of drug loaded strands for subcutaneous implants.

The extruders are equipped with melt pumps and pressure / speed control for accurate throughput of the line.

Through use of a multi-layer die, the strand is extruded directly into a water bath vertically. This process eliminates any influence of a calibration system and gravity guarantees the high precision in diameter and ovalness.

Controlled water flow ensures an absolutely calm water surface at product entry into the cooling vessel. The diameter range is between 1 mm to 10 mm at a maximum line speed of 25 m/min.

The touch screen control system is ergonomically designed and files all process and quality parameters.

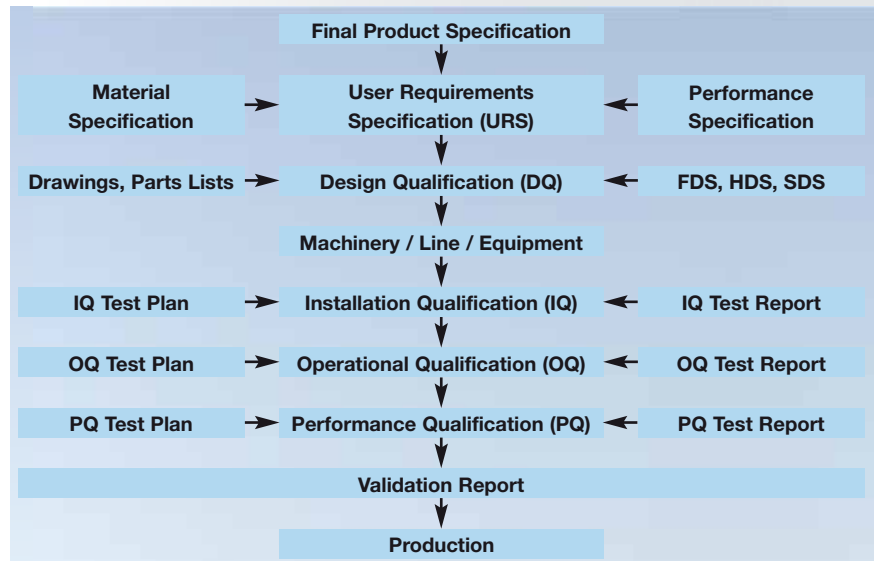


Validation Master Plan

COLLIN® has a well-trained and experienced team to give full support to fulfill all FDA requirements during

- Design
- Production and installation of the equipment
- Qualification and validation
- Documentation

The team follows the Validation Master Plan, which is tailored individually to the current project, strictly.



ISO 9001 and Design Rules

The quality management system of COLLIN® guarantees that all processes in all phases of machine design/construction are documented and controlled properly.

The basic rules outlined in 21 CFR, Part 11 are observed when designing proper FDA software.

Instructions for the mechanical and electrical design ensure that all FDA requirements concerning

- Materials
 - Surface shapes
 - Surface treatments
 - Electrical components
 - Wiring
 - Heating and cooling systems
- are satisfied completely.

Every detail of a COLLIN® line is designed to provide easy and fast access for cleaning and maintenance.



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