PHOTO: POLYCOMPOUND

Whether for medical, pharma or for engineering applications, demand for high cleanliness compound production is on the rise. Peter Mapleston learns more

Clean from start to finish

Mention cleanrooms to most plastics engineers and it is likely they will think of pharmaceutical production, manufacturing of medical and electronic devices, possibly plastics injection moulding, but almost certainly not compounding. It is simply not a term that is used much in the compounding business – but perhaps it should be. The reality is that if a processor working in a field such as medical does not start with a clean compound it is very unlikely they will be able to produce a clean syringe or similar device. To coin a phrase from the computer industry: garbage in, garbage out.

As it happens, there is plenty of expertise around covering clean compounding. Remember that many producers of twin-screw extrusion lines for plastics compound production also offer equipment that is not all that different in concept for pharmaceutical and food processing. However, a lot of what those equipment builders do in this area is covered by confidentiality agreements, so much of what follows in this article is based on input from a number of compound manufacturing companies considered to be leaders in the field.

Eric Ciemniewski is Plant Manager of the **Teknor Apex** facility at St Albans, in Vermont in the US, where the company produces its Medalist medical thermoplastic elastomers (the company also has a line dedicated to Medalist compounds in Singapore). "The adherence to CGMP protocols during line clearances ensures each recipe is free from foreign materials," he says (CGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA in the US and which provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities).

"The St Albans facility has a strong commitment to the needs of our customers and incorporates those requirements into their highly controlled processes. Everything from raw materials through packaging is considered when we produce products for our customers in the regulated applications, including machine lubricants," Ciemniewski says.

The Medalist production lines at St Albans and in Singapore both carry ISO 13485 certification. This international standard for quality management in medical manufacturing specifies systems for consistent compliance with regulatory and custom-

Main image: Swiss toll compounder Polycompound reports growing demand for its clean compounding capabilities from customers in the high performance power cable sector

er requirements and includes provisions for risk management, sterile manufacturing, and traceability. The comprehensive implementation program required for ISO 13485 certification requires focusing of the entire compounding operation on processes and procedures that maximise safety and reliability of the compounds supplied to medical device manufacturers.

Clean or white?

Lewiston, Maine, US-based **Compounding Solutions** implemented the use of a white room for all of its medical R&D and production materials back in 2012 (a white room can be considered very much like a cleanroom but without the certification). "Due to the extremely fine particle sizes of most colorants, the ability to obtain and then maintain the certification is extraordinarily challenging," the company says. "We conduct our own air quality reviews and have found that we meet Class 100,000 standards."

In a white paper, the company says that while gloved handling of finished products is a critical element in their customers' final assembly operations to help prevent excessive particle counts, many issues may be occurring before a part or product has been received to the plant.

"Depending on how your vendor has built and operates their facility it may be adding risk to your raw materials. Ceiling drop-downs for air, electrical wires or feed tubes can collect dust and other contaminates that can easily fall into open hoppers. Open water tanks capture the same environmental hazards as water baths do," it says. "Companies either have the ability to help with cleanliness issues or they do not. Most compounders do not run products under anything close to white room conditions."

The Compounding Solutions white room operates under conditions similar to a clean room using laminar air flow conditions to ensure that no

Below: Applications for the Teknor Apex ISO 13485 Medalist TPEs include syringe stoppers

PHOTO: TEKNOR APEX

ICMA delivers turnkey pharma solutions

In April this year, Italian twin-screw compounding extruder specialist **ICMA San Giorgio** delivered a complete system to a major European pharma group for direct compounding and extrusion of several types of TPE foils. The system includes gravimetric dosing units, a high-efficiency co-rotating twin screw extruder (ICMA MCM 60) and downstream equipment (three-roll calender and fully automated winding unit).

ICMA Managing Director Giorgio Colombo says the turn-key project involved complete engineering with several customised features closely tied to the customer's requirements, including solutions for assuring maximum cleanliness of the entire process line dictated by critical pharma applications. The line incorporates several digital solutions and sensor devices applied to key parts such as the calender and thickness control to achieve maximum accuracy during extrusion and the highest standard of safety for the operators.

ICMA has also just supplied a multinational pharma group with a turn-key line based on a 25mm compounding unit designed to produce several TPE recipes, Colombo says. "In this case ICMA was able to accommodate a very demanding customer with several customised features in line design and services."

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PHOTO: PLASTICS COLOR CORPORATION

Above: PCC's latest production line in Chicago was designed and installed by Entek

contamination enters the feeders of the compounding line. The walls and floors are all sealed so it is possible to carry out a complete wash from the ceiling to the floor. The company also took the precaution during construction of the facility to bring all electrical and water lines in from the ground up rather than using drop-downs, which can collect dust and other contamination. In addition, feeders for various additives are all covered and sealed under nitrogen.

The company says special attention is paid in the plant to water baths, which are areas where pyrogens collect easily. Thorough cleaning is carried out after each production run and changing the water in the cooling baths and scrubbing the tanks is standard practice.

Compounding Solutions has also recently announced plans to add a cleanroom, certified to Class 100,000, for medical compounding. It is scheduled to go into operation in January next year. "Clean room compounding is very rare and we continue to look to raise the bar and push boundaries of medical plastic compounding," said a company spokesperson.

The cleanroom investment is part of a 5,500m2 expansion of the Lewiston facility that has already provided the company with additional warehousing, post blending, packaging and shipping capacity, as well as housing a new compounding line.

PHOTO: COMPOUNDING SOLUTIONS

Above: Clean compounding at Compounding Solutions

Maintaining integrity

Integrity at all stages of the product development process "is absolutely paramount for medical device companies," says David Witt, a researcher with Chicago, US-based **Plastics Color Corporation** (PCC). "Medical device manufacturers have to be certain that for each product produced, every component and every process involved adhere to compliance standards."

PCC opened a 700m^2 "Plant Within a Plant" just over ten years ago for production of additive and colour masterbatch for medical devices. It says the facility was designed with input from medical experts who cited reducing contamination risk as a paramount concern. "We talked to customers in the market and asked what we and they needed to look like in five years," says Joe Byrne, President of PCC.

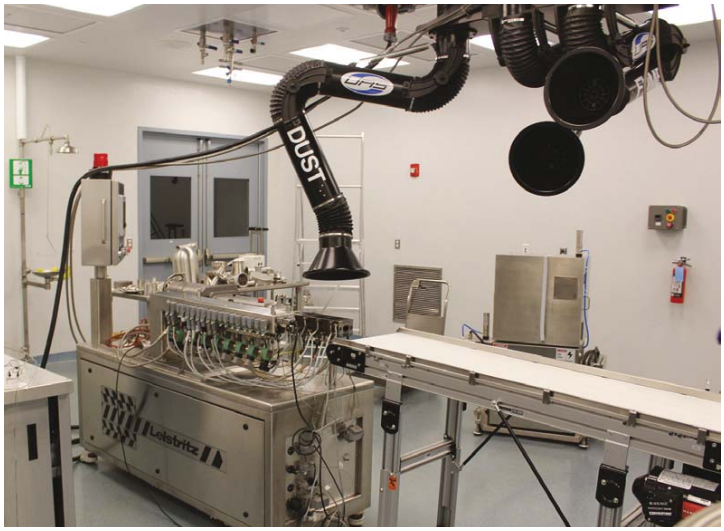
"The industry is moving toward quick-turn, just-in-time processing, as well as toward more closed-loop systems for clean compounding," says Byrne. "Today, we're making that all work in one facility. It has been important for customers to see how we handle materials and how the cross-contamination risk has been almost eliminated by using such equipment as a sterilised water bath utilising UV filtration and a closed-loop water system."

Adding capacity

Foster Corporation, headquartered in Putnam, CT, USA, is another leading supplier of custom compounds for medical applications. It was featured in an earlier *Compounding World* article on cleanroom compounding back in 2016 but has since added further clean production capacity.

"Foster's has built, and put into service, a new pharmaceutical facility across from our corporate facility. This is a state-of-the-art building with two

PHOTO: FOSTER CORP



Above: A compounding line in Foster Corp's latest cleanroom facility

clean rooms for projects/applications requiring pharmaceutical GMP protocols and documentation. In addition, a new R&D bay has been added for projects in the beginning stages of development that do not yet require the GMP requirements typically needed in a clean room," says Larry Johnson, Vice President of Business Development at the company.

"Foster's capability in medical device GMP compounding continues to expand, as our Medical Innovation Center allows customers to develop their products in a space that is designed specifically for medical polymer R&D." he adds. Capabilities available within the centre include downstream equipment to make extruded and moulded shapes, colour development, as well as compound formulation and development on compounding machines up to 27mm.

"The demands for cleanliness are getting more stringent as cleanroom capability is not being considered just for implants and pharmaceuticals, but also for non-implantable applications," he says. "Because devices are getting smaller, the criticality of the material in class II and Class III has risen, and is rising, to a level not seen before."

Johnson says that, in addition to the demand for clean compounding, medical device companies expect material inputs to be clean as well. This has created an enhanced market for materials that are either USP Class VI tested or ISO 10993 tested for medical device biocompatibility. "A key component of clean compounding is to have a strong quality system that is able to change with customer's needs. Foster's ISO 13485 Quality system does accomplish this objective," he says.

Foster, in turn, places high demands on its material suppliers. "We like to see the following key things: a robust quality system (we audit our suppliers regularly); enhanced and tighter material specifications; biocompatibility testing including USP Class VI and/or ISO 10993; no change agreements where suppliers must inform us (so we can inform our customers) when a material is either discontinued or a recipe constituent in the material is changed," Johnson says.

Beyond medical

Switzerland-based **Polycompound** also has some capacity for making very clean compounds but for a broader range of business sectors – mainly medium and high-voltage power cables as well as speciality film production. It also produces a few compounds for medical applications.

Business Development Manager Jan Schweizer says cable industry requirements in terms of cleanliness are intensifying. "Demands are rising mainly in the power cable sector, driven by government/EU projects to improve the power network in Europe. But technology is advancing too – cable producers have started talking about 800kV cables (today the maximum is about 550kV). This will require a totally new level of cleanliness," he says.

As a toll compounder, Polycompound does not choose its suppliers. "It is for our customers to select the right polymer producer as Polycompound is a 100% toll compounder. However, we do need stable high-quality raw material to produce such compounds," he says.

"Generally, when we speak about high clean products we try to protect the product from the environment," Schweizer says. "That doesn't necessarily mean that we need a clean room for doing that. We would rather focus on ensuring that material will always be in a controlled environment throughout the entire production process, from unpacking raw materials all the way to packaging granules into containers."

Unsuprisingly, Schweizer says that the costs involved in clean compound production are higher than standard compounding. "Most of the extra cost occurs due to special preparation of the compounding line," he explains. "Another cost factor may be special equipment required during production. All in all, highly clean products are about 20% to 40% more expensive to make. For small batches, it can be even much more."

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