PLASTICS CONSULTANCY NETWORK

Medical plastics

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A 'collision of misunderstanding'

(Some notes on medical devices and the contract moulder)

"The manufacture of plastics medical devices is a simple, low tech operation that any decent injection moulder or processor can do---so why do we have so many problems?"

Chief Executives, Purchasing Managers and R&D Engineers at biotechnology companies keep asking that question.

Were they microbiologists or biochemists, the question would be "Why do polymeric filter membranes behave so unpredictably?"

As a Technical Consultant, I am often faced with those very questions.

I trained as a Plastics Engineer before moving into the Medical Devices industry. How the two worlds differ! Plastics have evolved from the industrial chemicals world, where bulk synthesis, and cost containment in a fiercely competitive market have ruled. Plants which produce less than 2000 tonnes a year are non-existent. Medical devices are part of the burgeoning biotechnology industry where attention to detail is paramount, sophisticated bioreactions are used in everyday products and reagents are sold and used in microgram quantities.

So, when these two worlds of biotechnology and plastics meet, a "collision of misunderstanding" is perhaps inevitable. But meet they must and where they have learnt to understand each other and to use this understanding constructively, the benefits to both sides are enormous and offer depths of technology which were unimaginable even 5 years ago. The medical diagnostics industry has not only brought us instant pregnancy tests but has also given us simple to use, rapid tests for food microbiology, DNA profiling, infectious disease recognition. We also have needless drug delivery via skin patches or with high pressure air "guns". All these developments rely on contact between biological reagents or drugs and plastic surfaces. This interface between materials has led to many problems due to extraneous cross reactions which are created by the combination of chemicals which occur at this interface. These cross reactions are often not understood or foreseen because of a number of misunderstandings which have grown up over the years.

The most common misunderstandings

Let’s look at some of the most common misunderstandings:

1. Injection mouldings are made from "pure plastic", such as polypropylene.

2. "We do not use mould release therefore there cannot be any lubricant on the surface of the moulding", says the moulder.

3. Assembly of moulded parts to PVC tubing by solvent bonding is an easy and reliable process.

4. "Grade XX12A polystyrene made in our US factory is absolutely identical to grade XX 12B made in our European plant", says the raw material producer.

5. Pure nitro-cellulose membrane filter made by company X is the same as pure nitro-cellulose filter made by company Y.

All the above statements have relied on one common fallacy---that "pure" plastics exist.

In practice, there is no such thing as a "pure" plastic---at least as far as the user of plastic products is concerned. To make the material usable and processable, various additives have to be added to the base polymer such as lubricants, anti-oxidants, stabilisers or plasticisers. Although these "microingredients" are in small proportions, typically around 1 % or less, it is these chemicals which cause most of the problems when the materials are used in biological environments.

The same applies to polymeric membranes. Plasticisers are added to make naturally brittle materials tougher or surfactants are used to increase hydrophillicity.

Industrial plastics and bulk process filtration account for the major part of sales in the plastics and filtration industries. In these areas what matters most are the physical end properties of the product, so, the chemistry of the raw material is often modified in order to maintain these essential attributes and little attention is paid to the other effects the changes to raw material chemistry may have. Medical and biological applications only account for a small proportion of sales, but in the biological world, chemistry is all important. So, when the biological world uses materials whose chemistry is manipulated to satisfy the needs of the physical world there will be problems and we can start to see how the "collision of misunderstanding" occurs.

Clarity

If we look at the 5 misunderstandings listed above in more detail, the picture becomes clearer.

1.A material used for moulding, or extrusion, may contain a number of additives to make it process better or function better. These include:

- Lubricants, which can be "internal" for easier processing or "external" for easier release from the mould. The latter are designed to come to the surface of a moulding and can also be called 'slip agents'.
- Stabilisers and anti-oxidants to help the material withstand the heat of processing or to combat heat or light degradation during use of the component.
- Plasticisers to make the product more flexible.
- Anti-static agents to reduce build-up of surface charge on mouldings or extruded film. These chemicals are also designed to migrate to the surface of the product.

Some of these additives are by nature very reactive chemicals and can create adverse and undesirable side reactions with the biochemical reactions taking place on a diagnostic test device.

2. Mould releases, either silicone based or non-silicone types, as sprayed onto a mould to aid ejection of parts from the mould are usually "taboo" with medical mouldings BUT if the moulding compound has a surface lubricant or slip agent incorporated into it there could still be traces of lubricant on the surface of the moulding and the injection moulder would be quite innocent of any wrong doing.

3. Plasticised PVC has always been recognised as an additive laden material and many of the chemicals used are very mobile within the structure of the PVC. There have been a number of reported problems of solvent bonded PVC joints loosening after storage. This is due to the solvent setting up a reaction which causes the plasticiser(s) to migrate out of the tubing (especially when thick-walled tubing is involved). When the tubing forms the male part of the joint, loss of plasticiser causes shrinkage and contraction of the tubing and, hence, fracture of the bond.

4. Just as the base polymer has materials added to make it usable, so too do the additives themselves have impurities or other ingredients which can vary.

A material manufacturer may well make a popular grade of moulding compound in 2 or 3 plants over the world. Each plant will use the same basic chemical formulation but some of the ingredients will be sourced locally. So, if, say, calcium stearate is the lubricant used, it may be correctly called calcium stearate when sourced in the US or when sourced in Europe but there may be minute differences in chemical make up which are irrelevant as far as the moulding compound goes but which could cause serious cross reactions if a medical device user changed from using a moulding material made in the US to the same grade produced in Europe.

5. Nitro-cellulose filters are used for many biotech applications but it is a well-known fact that nitro-cellulose filters made by different manufacturers can behave very differently. Nitro-cellulose is neither moulded nor extruded into sheets of filter material but is processed by a casting technique. Nevertheless, the base material needs additives to make it usable - surfactants to make it hydrophilic and plasticisers to make it less brittle and it is variations in the chemistry of these additives which often cause the differences in performance characteristics between different manufacturers.

The solution

The SOLUTION to these problems is to create UNDERSTANDING THROUGH COMMUNICATION.

When a medical or biotech company needs plastic parts for a critical application, they should discuss this in detail with both the raw material manufacturer and the processor and get to know and understand the characteristics of the material grade involved. The processor, for his part, should understand about the needs of the medical customer and that material chemistry is often far more important than physical attributes. Learn and understand the needs of the other world and avoid these "collisions of misunderstanding".