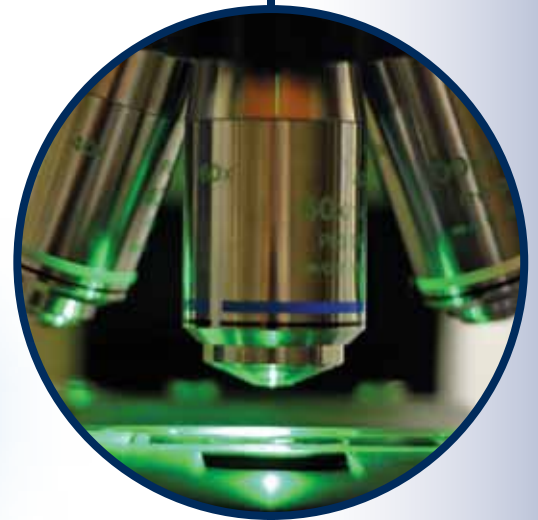


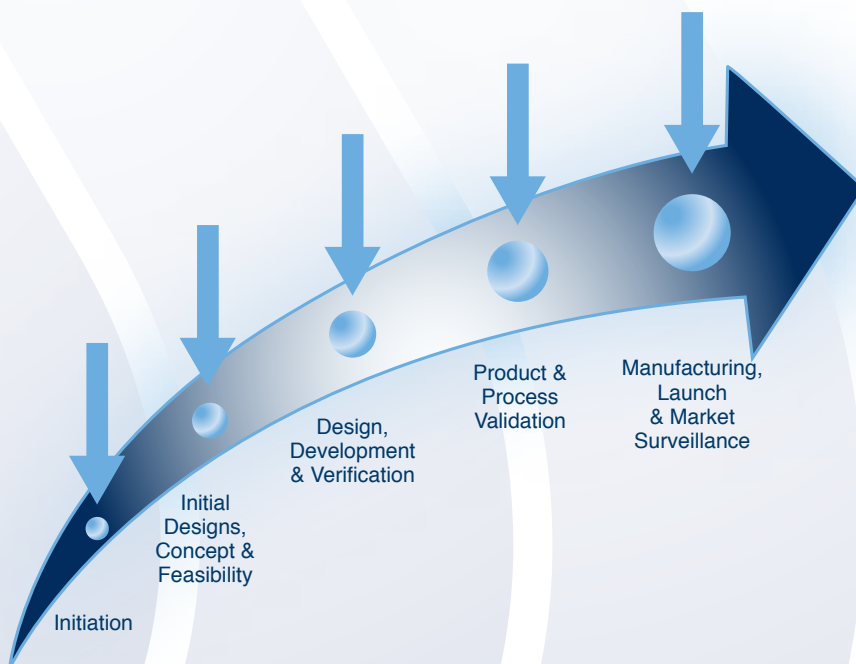
Benefits of Using a Contract Research Organisation for Medical Devices

Contract research organisations (CROs) are typically perceived as supporting medical device companies only with product testing and validation as part of their cGxP regulatory requirements. In reality they can do much more.

First, it is important to understand what CROs are. Medical device manufacturers will typically associate CROs with product testing, stability studies and clinical trials (hence clinical research organisation and contract research organisation being used interchangeably in these areas). Those from government or non-medical backgrounds will perceive CROs as research institutions that perform research sponsored by government and based largely in academia. The reality is that a number of CROs often have expertise in both areas, and in addition have specialist knowledge of the uses of materials and product design.



CRO can support at all stages of development



Why use a CRO?

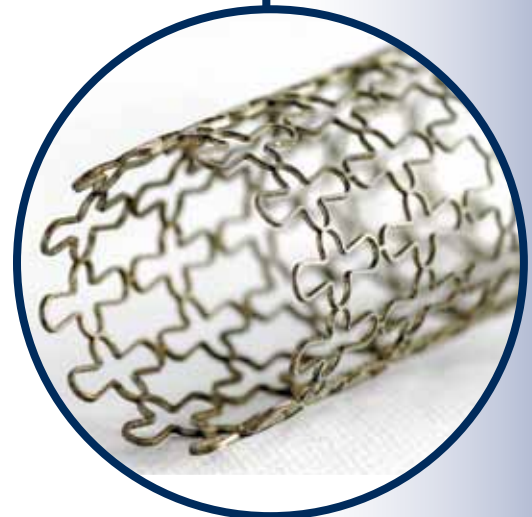
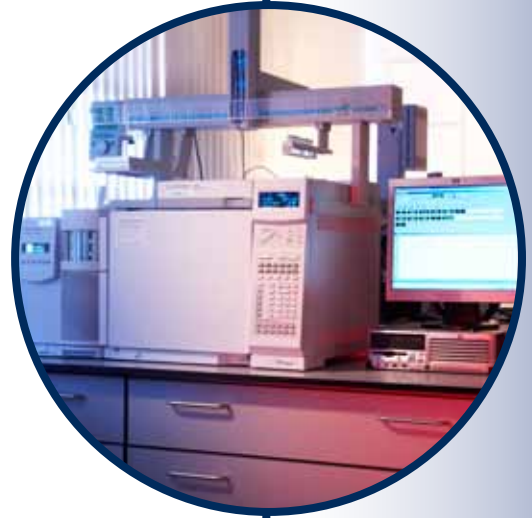
CROs can be viewed with scepticism by those who have never used them before and have concerns regarding loss of confidentiality and project control. These concerns can be mitigated by establishing a non-disclosure agreement and technical agreement in advance of initiating a project.

CROs bring with them a wealth of experience of working with many different products, regulatory regions, organisations and quality systems, which allows them to quickly integrate into the operations of the sponsor organisation.

Utilising CROs at all stages of the product design process allows the sponsor to quickly take advantage of different markets and opportunities due the immediate availability of expert personnel, knowledge and equipment. This avoids the need for the sponsor to invest in capital equipment or hire specialist staff.

For management, the true cost of a project can sometimes be hidden by internal administration costs and split revenues for personnel and facilities. When using CROs, the cost of projects are agreed in advance, therefore the cost of development is defined at the outset and the cost of a project can be directly controlled. Ultimately, the time taken to bring products to market will be shortened and will allow a company to expand into, or take advantage of, technologies that are not its traditional expertise.

“The importance of correctly identifying the technical requirements of the product at the early stage of design is demonstrated by the frequency of product failures investigated by Smithers Rapra”



Where to benefit most from CRO support

Having decided that CROs are valuable to your organisation, you will need to determine at which stage or stages of the development you will benefit from CRO involvement.

It is essential to identify CROs with the most appropriate knowledge and resources for your particular project. The advantage of incorporating the CRO at the early stages allows the project to be carefully planned and integrated into the design history file or stage gate processes. This will help identify design risk that could prevent potential issues arising in later design stages.

The importance of correctly identifying the technical requirements of the product at the early stage of design is demonstrated by the frequency of product failures investigated by Smithers Rapra. Smithers Rapra performs many investigations into why polymeric (plastic and rubber) products fail. Most failures are found to be due to poor identification of design risk (materials and product specification) at the initial stages of product development (**Figure 1**).

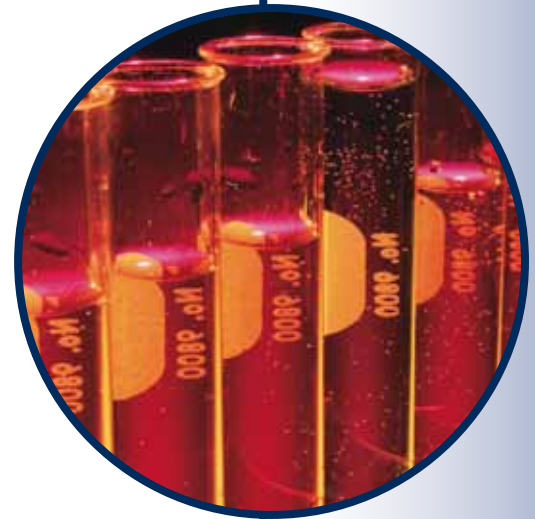
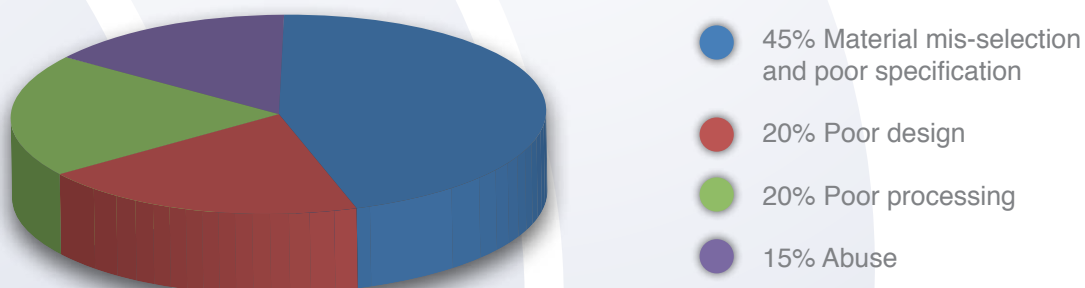


Figure 1: Causes of polymer failures



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The ability of plastics to be moulded into complex shapes at relatively low cost, low weight, good compatibility and controllable physical properties make them excellent materials for many applications. However, plastics bring additional considerations. Medical device companies have specific requirements such as long term supply security while only consuming a relatively low volume of polymer, controlled polymer formulations and unique requirements for chemical and biological compatibility. These requirements are often overlooked without awareness of the complex supply chain.

Medical device companies are specialists in product design and the clinical needs of a device, but can lack the in-depth knowledge of materials to be able to select the most appropriate material from the vast number and grades of polymers commercially available. The CRO can help to ensure that the correct materials are selected at the outset. For example the CRO could support the selection of a material from the many generic classes of plastics and thousands of named grades available, a selection process that may be daunting, if not risky, for those not familiar with plastic materials. This is because important considerations regarding the nature of plastics could be overlooked by those not experienced, such as taking into account the physical and chemical properties of a plastic that are dictated by the polymer chain (i.e. polyethylene, poly-vinyl chloride (PVC), polyamides, etc.) but can further be changed by the addition of other processing aids, stabilisers, fillers, etc. Some typical examples of medical device products and important material selection considerations are detailed below.



Table 1: Material Selection Considerations

Product	Environmental Considerations	Consideration for Material Selection
Tubing, blood bags, catheters, drug delivery systems	Sterilisation, body fluids, storage conditions	Biocompatibility (ISO 10993), Extractables and Leachables, labelling requirements for DEHP*, shelf-life (long term stress), Environmental Stress Cracking (ESC) due to polymer interactions, polymer creep related failures.
Surgical equipment	Sterilisations, body fluids, storage conditions	Biocompatibility (ISO 10993), Extractables and Leachables, physical properties such as hardness, impact strength etc, shelf life, etc.
Electronic monitoring devices	Body fluids, cleaning fluids, other materials	ESC (compatibility of polymers, cleaning fluids, seals etc.), creep and fatigue (cyclic loading), aesthetics, etc.

DEHP- diethylhexylphthalate, *See essential requirements of the Medical Device Directive 93/42/EEC and 2007/47/EC.