



A person wearing a full white protective suit, including a helmet and a clear face shield, is working in a laboratory. They are wearing blue gloves and are positioned at a workstation. On the workstation, there is a laptop computer, a white container with a red lid, and another white container with a red lid. The person is looking at the laptop screen. The background is a plain wall with a window. The overall lighting is warm and orange.

**SAFETY &  
QUALITY**

The need for safety and quality has risen sharply over recent years. Safety concerning our food, the medicine we take, the reliability of our cars, a safe workplace and a sustainable living environment. The absence of either of these can have far-reaching consequences. Your reputation could suffer, the environment could be in danger, the health of your employees could be at risk and even the continuity of your company could be jeopardised.

CurTec puts the highest priority on safety and quality. Our products have to be safe and certified and possess a quality that meets the expectations and requirements of our clients. Safety and quality are the driving forces that motivate our employees. This means that we are constantly striving towards making improvements in working conditions and work methods.

In this 'Vision on Quality' you will read about our daily efforts to improve the safety and quality of your packaging. CurTec is able to count many companies in the pharmaceuticals and chemical industries among its clients. We are convinced that our way of working and reliability has a significant influence on our customer's satisfaction and the present and future success of our company.



**HYGIENE  
MANAGEMENT**

When you think of hygiene management and HACCP (Hazard Analysis and Critical Control Points), you will probably think of food products first. However, the ideas behind hygiene management are not just limited to the food industry. Both the pharmaceutical and chemical industry also pay considerable attention to this. Furthermore, in recent years, the focus is no longer on just the production process, but the entire supply chain.

Contamination and quality-loss constantly threaten your products. When packing and shipping, you want to take as few risks as possible. Cleaning a contaminated product without causing irreparable damage is difficult and expensive. It not only leads to financial loss, but also damages the image of your company. Clean, robust packaging reduces these risks considerably.

CurTec wishes to contribute to the cleanliness performance of our clients by supplying optically clean packaging. We are HACCP-certified according to Codex Alimentarius (2009) and are currently preparing the implementation of ISO 22000 and ISO 15378 (cGMP). If you have specific cleanliness requirements for your packaging, we would be pleased to review them with you.



**DRUG  
MASTER FILE**

A Drug Master File (DMF) is a document that is submitted to the Food and Drug Administration (FDA). A DMF contains confidential and detailed information about facilities, processes and/or articles which are used in the production, processing, packaging and storage of medicines destined for human consumption.

The submission of a DMF is not required by law or FDA regulation. A DMF is submitted by a manufacturer (also referred to as a holder) of medicines, or in the case of CurTec, the manufacturer of packaging for medicines.

The information in the DMF can be used for new experimental medicines (IND), new uses for medicines (NDA, ANDA), other DMFs, for export applications or amendments and additions to one of these categories.

CurTec's DMF is filed under number I6388.

The FDA can always decide to inspect a DMF when any of the following parties submits a request to refer to a DMF:

- A sponsor of a new medicine
- An applicant for a new use (NDA, ANDA) or for export purposes
- Another DMF holder

The holder of the DMF (CurTec) must first grant permission in writing by means of a Letter of Authorisation (LOA). The FDA receives a copy of this letter.

### **LOA**

*A written declaration by the holder, an appointed agent or its representative that permits the FDA to refer to information in the DMF to support another submitted DMF. The applicant, sponsor or other holder that is able to refer to the information in a DMF must be able to present proof and therefore receives a copy of the Letter of Authorisation (LOA).*





**SAFETY:  
FROM PHARMA  
TO FOOD**

How do you keep a grip on the quality and safety of your food ingredients? Lots of things can go wrong in producing an end-product. The EU and US have strict laws and regulations, particularly for pharmaceutical and food packaging. As a producer, you are ultimately responsible.

Prevent damage to your products and your image with good packaging. CurTec offers you the certainty of packaging that complies with the laws and regulations.

All CurTec products, with the exception of conductive drums, are suitable for pharmaceutical and food applications, which means that they:

- Comply with the GMP guidelines
- Comply with all applicable EU directives (1935/2004, 10/2011, 2023/2006)
- Comply with FDA regulation CFR 21 177.1520 (Olefin polymers)
- Are produced according to a strict and certified hygiene management system



**SAFE  
TRANSPORT**

Shipping goods gives rise to increased risks. Goods may get damaged in transit or during loading and unloading. Also, companies that outsource their transport have less control over the handling of their products. Fortunately you can insure yourself against possible damage. Consider that prevention is always better than a cure.

CurTec packaging is thoroughly tested for strength. It has been designed to withstand extreme strain and sudden impact during transport. Naturally all packaging complies with current legislation and rules on the transportation of goods. To ensure the safety of people and protection for the environment, CurTec manufactures packaging for hazmat that complies with UN regulation and bears a UN mark.

### ***Transport of dangerous goods***

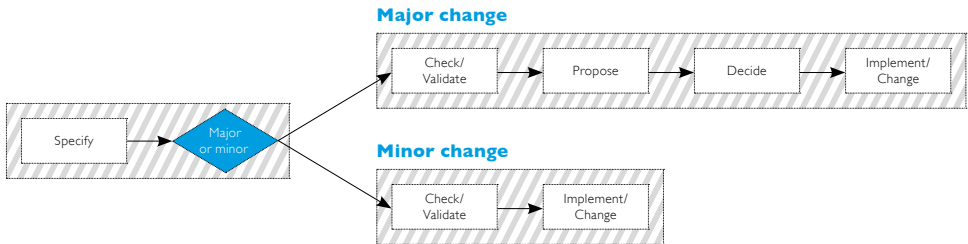
*Do you ship hazmat? Then this calls for extra care. Each year, 54% of dangerous goods are rejected for shipment upon initial inspection because of unsuitable packaging or securing. This often incurs high costs.*

A person wearing a blue long-sleeved shirt is shown from the chest down, sitting at a desk. They are holding a white pen in their right hand and writing on a document. The background is blurred, showing what appears to be a computer monitor. The entire image is overlaid with a green and yellow gradient, with the text 'GET A GRIP: CHANGE CONTROL' in white, bold, sans-serif font in the lower-left quadrant.

**GET A GRIP:  
CHANGE  
CONTROL**

Proper change control goes beyond your own organisation. It encompasses the entire supply chain. In other words, it includes the work activities performed by your suppliers and their suppliers. Choosing suppliers who have their change control in order enables you to keep a grip on this. Furthermore, it is good to:

- Make arrangements with your suppliers about notifying changes
- Make arrangements with your suppliers about approving changes
- Establish the agreed terms in a supply agreement and/or a quality agreement.



Any change can have far-reaching consequences for your product. Because CurTec packaging is clean, safe and fully certified, we have a change control procedure. This not only allows us but also you to maintain a grip on quality.

*‘ Change control:  
a systematic approach for the management  
of all changes in a product or system ’*

### **What is considered a change?**

*All changes to the product or production process which might - intended or unintended - influence your application. Some examples of changes:*

- *Product changes (material, production, specification)*
- *Facility changes (that might impact the product or quality)*
- *Changes in controlled documentation*
- *Changes to legislation and regulations*



**MATERIALS  
SAFETY**





Because the presence or migration of certain substances can pose a threat to your product, you want to be sure that the materials used in your packaging are safe. CurTec only uses raw materials from reliable European suppliers. We comply with current legislation and, in close cooperation with those suppliers, aim at staying ahead of any changes as well.

Do you work with content that is classified as hazmat? If so, use your Material Safety Data Sheet (MSDS) to determine the suitability of a certain packaging. Need help? CurTec will be glad to assist you.

### **Regulatory Affairs**

*In case you would like to know which regulatory standards CurTec products meet, please consult our Regulatory Affairs Datasheet: [www.curtec.com/irads](http://www.curtec.com/irads).*

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DISTRIBUTION WORLD-WIDE

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INTERNAL

ERIAL

EXTERNAL

# SUSTAINABILITY

**MOST RECYCLED  
PLASTICS (WORLDWIDE):**

PET PP HDPE LDPE PS

RECYCLED MATERIAL  
(CLOSED-LOOP)

**NO WASTE POLICY = SEPARATE AND ALL THE WASTE TO BE CONVERTED IN**

95% of production process waste is coming from the p  
Remainder (5%) is sold to certified bodies.

At CurTec, safety and quality are closely related to sustainability. That is why we use our knowledge and skills to build a secure future on the economic, ecological and social front. This means we continue to move forward and always strive to improve.

### ***Our people: the key to the future***

Although more and more processes are being automated, people are and remain the key to our success. That is why we make extra investments in a HR policy that is focused on the stages of life, vitality, education and civic integration. In addition, we guide the transfer of internal knowledge and acquired practical experience.

### ***Reducing energy***

For many years, CurTec has been working on a long-term plan to reduce its energy consumption. Until today we have achieved energy savings of more than 30%. Our goal is to increase these savings even further.

### ***New materials***

We like to look beyond tomorrow. We research new techniques and materials to make our packaging even more sustainable. At the moment we investigate the use of biopolymers, better known as bio-plastics.

A photograph showing two men in a computer lab. One man, wearing a light-colored striped shirt, is pointing at a computer monitor displaying a 3D model of a bucket. The other man, wearing a dark shirt, is holding a yellow highlighter and looking at a document. The scene is lit with a warm, orange glow. The text "QUALITY & DESIGN" is overlaid in white, bold, sans-serif font in the lower-left quadrant.

**QUALITY &  
DESIGN**

A reliable packaging has to comply with laws and regulations and must be well-designed. The right design not only ensures that packaging represents your organisation in the best possible way, but it also brings ergonomic and logistical benefits. The R&D department at CurTec works to GMP guidelines. We develop new packaging and improve existing packaging on the basis of these guidelines.

R&D also has an advisory role in sales. For instance, one important factor when choosing materials is to guarantee a stable production process and avoid migration of substances.

## **Your own custom packaging**

CurTec can design a packaging that precisely meets your requirements and that helps you to reduce costs and increase profits. CurTec has years of experience with the analysis of supply chains and designing custom packaging.

*‘ We always try to design the most suitable packaging in the most affordable way ’*

Together with you, our skilled R&D people will examine your requirements which may include colour, strength, budget and design but also pallet optimisation. After the planning and development process and approval of the initial product designs, we will subject the draft packaging to various tests. The final result is a UN certified, high-quality packaging that meets your specific requirements.



**CurTec International**

Spoorlaan Noord 92

5121 WX RIJEN

The Netherlands

UK & Ireland: +44 20 3514 4624

North America: +1 908 450 9816

All other countries: +31 88 808 2052

[curtec.en@curtec.com](mailto:curtec.en@curtec.com)

**[curtec.com](http://curtec.com)**