

GLOBAL GMP SOLUTIONS FOR FOOD PACKAGING AND OTHER FCMs

REGULATORY COMPLIANCE SERVICES

GMPs ensure that materials and articles are being consistently produced and controlled to achieve compliance with applicable regulations and standards.



GMPs prevent contamination during the entire production lifecycle for food contact materials (FCMs) and articles - from the raw materials selection phase through to storage and transportation. With the sufficient risk assessment procedures, quality control measures and documentation systems in place, companies can ensure that their products are fit for their intended use, not endangering human health or causing unacceptable changes in the composition or organoleptic properties of food.

Regulatory Background

There are legally binding regulations in force in the EU, U.S. and China that specifically require companies to have good manufacturing practices (GMPs) in place for the production of materials and articles intended for food contact.

The GMP regulations are as follows:

- EU - European Commission **Regulation (EC) No. 2023/2006** "On good manufacturing practice for materials and articles intended to come into contact with food"
- EU - **Regulation (EC) No 282/2008** "On recycled plastic materials and articles intended to come into contact with foods" amending Reg. (EC) No. 2023/2006
- USA - **FDA Title 21 CFR 174.5** "General provisions applicable to indirect food additives"
- China - National Standard for Food Safety **GB 31603-2015** "General Hygienic Specifications for Production of Food Contact Materials and Articles"

In addition, some countries, such as Japan or the countries under Mercosur have regulatory frameworks in place for food contact materials. These frameworks set general criteria around food contact packaging safety, and often includes requirements for GMPs.

A well-established quality system within a GMP program will address any material, product safety or contamination related risk or incidents. Companies should also consider implementing sufficient hygiene and housekeeping measures, having the proper documentation and labelling systems in place for traceability, conducting training for their personnel, and having an internal audit plan for GMP compliance.

Our GMP Services

GMP regulations apply to different sectors and stages of the FCM supply chain, and the rules that govern each industry may vary. While there is no standard available implementing the regulatory requirements for GMPs for the FCM industry, Intertek Assuris experts apply an integrated approach and provide support as a 2nd party to help customers achieve GMP compliance. Our approach is aligned with relevant industry guidelines and food safety standards for packaging, however, our GMP audit service is not an audit service for standards.

Our services aim to identify gaps in the key GMP procedures for the production lifecycle starting from raw material handling, packaging and finally storage of the final product. Recommendations on the corrective actions to address the gaps are also included.

Our Services Include:

- GMP regulatory training
- Support with risk assessments of production sites to identify critical control points
- Analytical testing support (i.e. NIAS screening)
- 2nd party GMP audit
 - Desktop review of existing procedures
 - On-site audit
 - Deliverables include:
 - Corrective action plan for GMP compliance
 - Tailored GMP checklists / audit template (for internal audits)
 - GMP statement for client communication/supporting documentation

All of our services can be provided on-site or conducted remotely.

FOR MORE INFORMATION

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 intertek.com/regulatory/food-contact