EuPIA GMP Presentation

Mike Simoni, September 2016

- In many parts of the world, there is a legal requirement that companies producing food contact materials have a GMP policy.

  – In Europe this comes from the European regulation (EC) No 2023/2006.

  – In the USA this comes from the FDA regulation 21 CFR Part 110.

  – In China this comes from the National Standard of the People's Republic of China GB 31603-2015

- Many ink trade associations have created Good Manufacturing guides that when followed will ensure compliance for their members.

  – EuPIA (European Printing Ink Trade Association) has recently updated its GMP policy. This became public on 31st March 2016. The reason for the extra detail was to create a level regulatory playing field in the ink / coating industry.

- www.eupia.org

Published 31st March 2016

- The new GMP is publically available on the EuPIA website, currently in English & German.

- The Good Manufacturing Practice (GMP) was prepared by large task force in which almost all of the EuPIA member companies (both large and small) were represented.

- This Good Manufacturing Practice (GMP) aims to assist in controlling food safety hazards in the design and manufacture of inks, varnishes and coatings designed to be printed onto Food Contact Materials, and formulated for use on either the non-food contact or the food contact surfaces of food contact materials.

- The March 2009 GMP was 13 pages long. This GMP document is 47 pages long, it describes in much more detail the processes required for compliance.

- In some cases the GMP includes flow charts and worked examples to clarify processes.
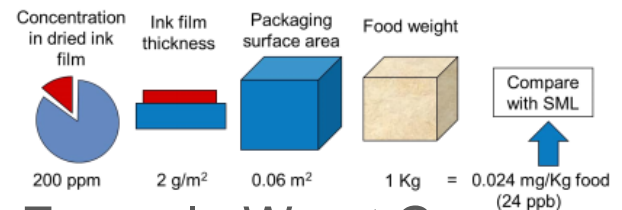

FMEA column headers (assessment of status before risk minimisation means)

- Example template for FMEA style risk assessment
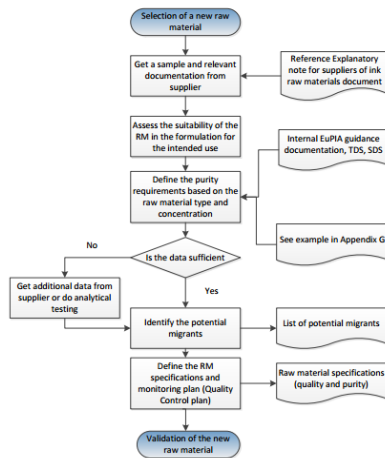
- Example flow chart for new raw material introduction

- Example Worst Case Calculation

- The EuPIA GMP recognises that there is a higher potential risk for contamination & hygiene issues associated with Direct Food Contact (DFC) inks & coatings, due to the much shorter diffusion path. To mitigate this risk the following controls are implemented:

  - A more rigorous process of selection of raw materials, and formulation design, to minimise non-intentionally-added-substances (NIAS) as impurities. Note that this does limit the number of raw materials that can be used.

  - A more controlled process for manufacture in which contamination control (from previous batches & cleaning materials), and hygiene control are implemented.

Differences	GMP March 2009	GMP March 2015
Scope	Non-DFC surfaces of food packaging only	Both DFC and non-DFC surfaces of FCM's
Level of detail	Overview	Greater level of detail, includes flow-charts & worked examples
Risk Assessment	Not explicitly mentioned	FMEA process, including guidelines for scoring
Demonstrating compliance	Not explicitly mentioned	Evidence based, example analytical result validating cleaning process
Auditing	Internal audit using checklist	External audit by customers, in addition to internal audits
Updating	Last updated 2009	Will be regularly updated to reflect changes

- The EuPIA GMP is a stand-alone GMP Standard. EuPIA members are expected to adopt this GMP.

- EuPIA members may in addition to the EuPIA GMP also choose to comply with IFS 6 (International Food Standard) accredited standards such as BRC IOP or ISO22002-4. Many of the processes in the EuPIA GMP are similar to those in the BRC IOP and ISO22002-4 standards.

- The EuPIA GMP has been written by the ink industry and for the ink industry, whilst both the BRC IOP and ISO22002-4 standards are more generic and need interpretation to properly fit for our industry.

- The EuPIA GMP is designed so that our customers and Brand Owners can audit EuPIA members against this standard. When audited the expectation is that EuPIA members will be able to show:

- Internal GMP audits
  - This should include actions generated from these audits, people assigned to completing these actions and a timescale for completion. If the GMP process has been in place for some time there should be a list of completed GMP actions.

- An FMEA based Risk Assessment detailing contamination and hygiene risks.
  - For the highest risk scores mitigating actions will have been put in place to reduce the risks.

- GMP Compliance is a process of continuous improvement.

- The EuPIA GMP standard compliments the work that members are doing related to:
  - Quality
  - Environmental
  - Occupational Health & Safety

- Members are finding that implementing the EuPIA GMP is resulting in actions, and improvements, that are occurring across the printing ink industry.

Thank you.

Any questions ?