

*IPAC-RS SYMPOSIUM on Extractables in Materials for IONDP, Supplier GMP Workshop
and Supplier GMP Guideline*

Tuesday, February 13, 2007 – Wednesday, February 14, 2007

PANEL DISCUSSION QUESTIONS

- 1) *What does Change mean to Diamond Polymers?*
- 2) *What does Extractables mean to Diamond Polymers?*

1) What does Change mean to Diamond Polymers?

- DPI is both a producer and compounder of plastic materials to a wide variety different industries. Material properties are dictated by our customers, the OEMs and their end-use markets
 - 1) e.g. Automotive vs lawn & garden vs medical vs pharmaceutical device materials
 - 2) Establishing accurate and reproducible testing protocol for plastic materials is one of several important steps to insure both the reproducibility and performance between different production lots of the ‘same’ material and eliminate the ‘change’ aspect and what it might affect later during the final part application.

- The issues formulations & Change
 - 1) All DPI formulations are secured within our computer network with “no” changes or “substitutions” noted
 - 2) Concerns => “What is the suppliers of the raw materials called out in the formulations make a change without prior notification to DPI”

- The issues of raw materials & Change
 - 1) All suppliers of raw materials to DPI which are processed into plastics used in medical or pharmaceutical devices have been made aware of their requested responsibilities to notify DPI if any formulation or raw material changes that are planned or implemented in those raw materials purchased by DPI. The concern is ‘how’ DPI can control the nature of materials purchased from our suppliers?
 - 2) These “changes” are most concerning to DPI

- The issues related GMP & Change
 - 1) Good Manufacturing Practices are essential to prevent contamination and establish the necessary assurances and controls within manufacturing facilities that supply materials to the medical or pharmaceutical industries.
 - 2) Preventing any contamination as well as insuring that the manufacturing “process” remains “in control” will further assure product quality and consistency and reduce/eliminate variation issues related to ‘hidden change’

- The issues of plastics processing and change
 - 1) DPI processes plastic materials on a variety of plastic processing equipment – twin screws and single screws
 - 2) Any changes in the ‘screw design’, processing temperatures, feed rates, screw speeds, etc. will often be followed by changes in the final physical properties or even possibly the extractables results.

2 What does Extractables mean to Diamond Polymers?

- The importance of identifying **KEY** additives or other extractables that play critical roles in the overall performance of the final medical device represents only one aspect in the total quality assurance of a plastic material that has yet to be formed into the final part for a medical or pharmaceutical application. Testing for the physical property requirements is equally as important as the proper processing the material into the final parts and their respective assemblies.

- From DPI’s perspective, the identification of **KEY** extractable materials are crucial => antioxidants, lubricants, residual monomers, etc.

- 1) FDA and other compliance requirements
- 2) Final part assembly and color/aesthetics

- Open and honest discussions between all parties are necessary along with trust in order to collectively:

- 1) Identify the key ‘extractables’ and their ultimate effect upon part performance
- 2) Are there overlapping “extractable” roles the FDA?
- 3) DPI is often involved in the development of ‘new’ extraction methods for key additives – this is very important – should also involve the manufacturer in DOE design optimizing raw material lots, processing conditions, blending conditions, etc.
- 4) It is essential that all parties be involved from the onset for the design of medical devices

- Extractable results are determined **AFTER THE FACT**. This means that materials have already been produced, packaged and remain on QC Hold until the results are determined to be within specification.

- What precautions exist to insure test results within established extraction specifications

1) DPI notifies all ‘key’ suppliers that critical components “X,Y or Z” will be extracted in the final product => ‘any’ changes in their product(s) must be advised to DPI immediately.

2) DPI establishes critical procedures to insure accurate weigh-ups and blending to insure that extraction results fall within determined limits.

3) *Should* DPI develop an ‘in house’ extraction laboratory?

4) *Should* DPI expand the “A2LA” certifiable scope to include ‘in house’ extractions?