

# Confidential (not for general distribution)



## Full Minutes PQRI PODP Leachables and Extractables Chemistry Subteam September 17<sup>th</sup>, 2009

### Minutes:

Meeting started at 10.15 AM EST

The goals of the chemistry sub team were to:

- Agree on the stage 1 protocol
- Organize distribution of the test materials
- Identify where the resources will come from

### Protocol

The chemistry team reviewed the stage 1 protocol and agreed on the output. The protocol is designed to test materials and not look at the effects of process e.g. radiation on the materials themselves. In addition large volume parenterals and ophthalmics are outside the scope of this protocol. The team also agreed to substitute special case impurities with targeted extraction techniques.

We will address the outstanding issue in the protocol around system suitability. They will report back at the next monthly meeting.

Member will look at how data will be reported.

### Distribution of Materials

The study coordinator will organize and arrange the distribution of materials for the individual laboratories.

### Resourcing

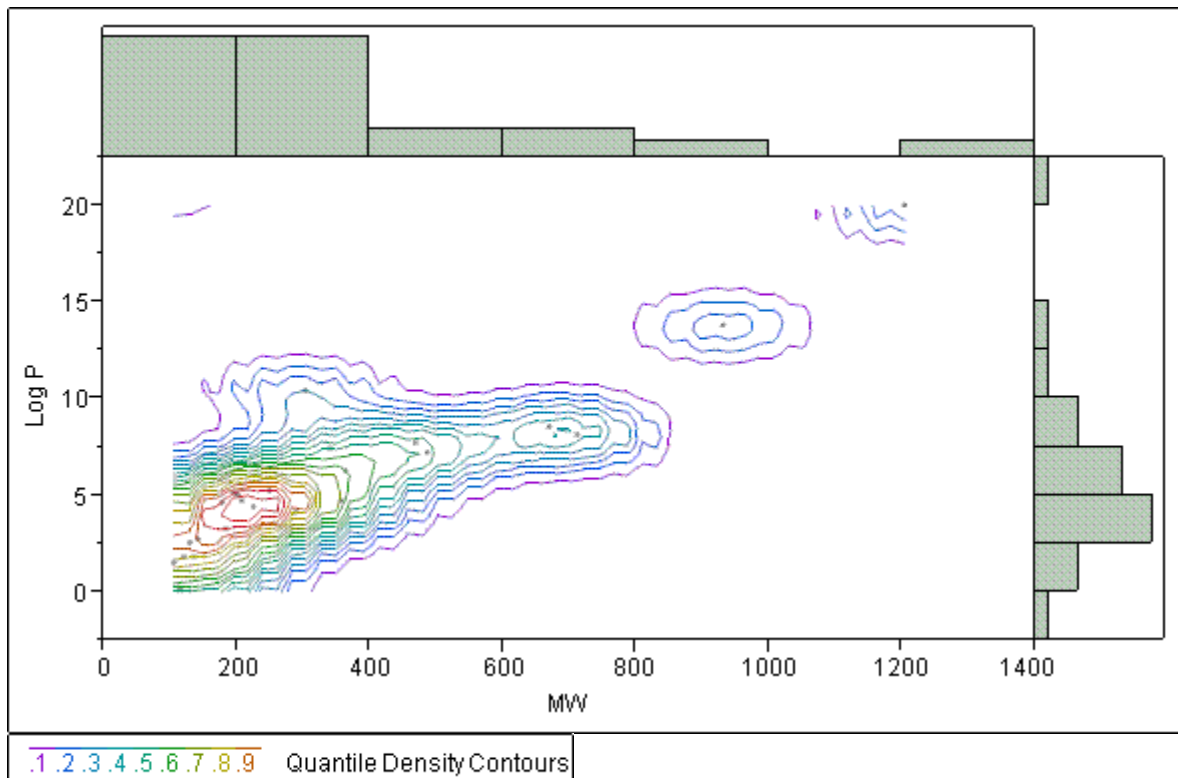
The members committed to conducting the testing on the following systems as outlined in the protocol.

Member outlined an approach for the identification of test procedures to detect extractable compounds. The approach is based upon an analysis of the chemical and physical properties (e.g., Log D, Log P, UV max abs., molecular ion, boiling point, etc.) of known extractable compounds and identifying similarities among these compounds. The comparison is done by plotting the values of molecular weight vs. Log D, Log P vs. absorbance vs. etc in a multi-axes format (see example see graph below), then finding regions in the plot where there is/are cluster(s) of data points. The density of the data clusters would indicate conditions that are common to these compounds. With this information, analytical techniques (e.g., HPLC or GC)

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and operating conditions could be tailored for the analyses of extractable compounds using this approach.

## Data Density Analysis using a contour plot format for Molecular Weight vs. Log P values



> 90% of the data is located in the range of 100 to 300 mw and log P values of 2.5 to 7.5. Further characterization can be accomplished by addition more axes (e.g.,  $\lambda$  max wavelengths, boiling points, etc.). Let me know if you need additional information about this analysis.

Meeting concluded at 03:45 PM EST.