



You are here:HomeArticlesInterview with Dr Mario Rocci – ICON

## Interview with Dr Mario Rocci – ICON

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**Mario Rocci (ICON, USA) spoke to Bioanalysis Zone in May 2011.**

### **What is your opinion on the current state of the pharmaceutical industry?**

The pharmaceutical industry is in a substantial state of flux. A significant number of blockbuster drugs will be losing patent protection within the next few years and pharmaceutical companies are hard at work trying to identify potential new drugs for development with mixed success. To help improve this success, the better part of this decade has been consumed with efforts to evolve pathways that translate basic research findings to the bedside quickly and efficiently.

To further complicate the landscape, the traditional paradigm for drug research and development and its attendant costs are unsustainable moving forward. Scientific advances in pharmacogenomics indicate that many disease states are heterogeneous in nature, suggesting that we will be more successful in treating such diseases by developing highly targeted therapies for specific subtypes of patients with the disease. This creates further pressure to reduce the cost of drug development since the market potential for highly targeted therapies may not be as high as that enjoyed for 'blockbuster' drugs. So, as such, there is much work ahead for the industry.

### **What is the biggest regulatory challenge facing bioanalysts today?**

I believe the biggest regulatory challenge resides in the global harmonization of guidelines related to the conduct of method validation experiments and bioanalytical sample analysis. While the science that underpins the bioanalysis field continually evolves we are in a position from a scientific viewpoint to harmonize regulatory standards globally. Good scientific practice knows no geographical boundaries. In the interest of efficiency and the desire to reduce the ever escalating cost of drug development, I believe it is imperative that this initiative is given priority among the various regulatory agencies.

### **How is your time balanced between managing the laboratory and business aspects of the global bioanalytical services at ICON?**

There is no set schedule that consistently works to meet the needs of our facilities and clients. I believe that if we pay the greatest amount of attention to science, quality and service delivery, then our business will continue in its success and growth trajectory. We are very fortunate to have a top-notch team of scientists, support staff and management that continually focus on maintaining and improving our laboratory offerings. Over the last several months, our upper

management team has been focused on laying the groundwork for the geographical expansion of our bioanalytical services into Asia.

### **What would you say have been the most important milestones during your time in bioanalysis?**

I have studied/worked in the bioanalysis field for approximately 35 years, so some of the important milestones I have witnessed are taken for granted today. One of them is the advent of HPLC as a bioanalytical tool. Another is the widespread use of integrators and later data acquisition/processing/LIMS systems to process and manage laboratory data – it sure beats measuring the heights of chromatographic peaks with a ruler! Though GC–MS/MS technology existed in the 1970s, the thought of using such technology with robotic autosamplers for bioanalytical applications was uncommon to say the least. Later, the introduction of LC–MS/MS technology revolutionized small-molecule bioanalysis and is now being used with more frequency to analyze molecules of higher molecular weight.

In a totally separate vein, I have witnessed the migration away from radioimmunoassays toward non-radioactive immunoassay technologies, with a recent proliferation in the types of platforms that can be used to analyze macromolecules, including biomarkers.

### **How has our understanding of incurred sample reanalysis developed over the last 5 years?**

Several years ago, the US FDA opened a dialog with the scientific community related to the need to conduct incurred sample reproducibility (ISR) experimentation in order to provide scientific evidence that methods were reproducible under sample analysis conditions. To the best of my knowledge, there were two major factors responsible.

The first was that certain regulatory inspections conducted in the US revealed the potential for non-reproducibility in bioanalytical LC–MS/MS results. In addition, well respected scientists, such as Surendra Bansal, discovered that certain situations such as inadequate mixing of the sample could produce heterogeneity that might result in reproducibility problems.

This new area of ISR testing was met with some skepticism by the industry at the time, and several workshops and symposiums were held that discussed this topic in great detail. Our laboratories, as well as those of others, published our thoughts on how ISR testing should be approached and in 2009 guidelines for this type of testing were published by Fast *et al* [1].

Now that we have had some time to evaluate its impact, I think most of the scientific community would agree that ISR testing is value added and that in some cases non-reproducibility can be observed in results from one occasion to the next. In our experience, the majority of instances where such non-reproducibility occurs is when there is analyte instability in the incurred sample that is not observed in quality control samples. Thus, the conduct of ISR testing can provide a valuable level of confidence in the reproducibility of our analytical results.

### **What do you think will be the hot research topics in the next few years?**

I think one of the hottest research topics will be the analysis of large molecules using LC–MS/MS

techniques. Though we are progressing in this area, there is still a long way to go. This capability will permit sensitive and specific bioanalysis to support both the development of new protein therapeutics as well as biomarkers. This techniques will add to the array of immunoassay techniques that can be directed toward such work.

### **Bibliography**

[1] Fast DM, Kelley M, Viswanathan CT *et al.* AAPS workshop on current topics in GLP bioanalysis: assay reproducibility for incurred samples – implications of crystal city recommendations. *AAPS J.*11(2), 238–241 (2009).