

Exploring the Development side of R&D

Tom Catalano*

PharmChem Analytical Consultants, LLC, USA

***Corresponding Author:** Tom Catalano, PharmChem Analytical Consultants, LLC, USA.

Received: February 18, 2016; **Published:** July 06, 2016

Although my educational background has been in Pharmacology and Toxicology, I have spent 32 years in Pharmaceutical R&D mainly supporting the development of new chemical entities into new therapeutic agents. I am happy to see a journal like the EC Pharmacology and Toxicology is open to publication that deal with Development side of Research. I believe that researchers can benefit by being exposed to the regulatory demands of taking their proposed lead compounds through the development cycle and resulting in the registration of the product. Currently the pharmaceutical industry is demanding a closer relationship between discovery and development, so that issues which could result in dropping the lead compound later in development, where the costs are much higher, can be recognized earlier and resolved. Areas such as Solid State, Polymorphism, Salt form determination, Genotoxic impurities, and more selective and sensitive methods of analysis can be enhanced by having stronger interaction between discovery and development. I have 32 years in the Pharmaceutical Development Industry in various positions, which led to a multitude of experience in providing support to dosage forms and drug substances including biologicals. The EC Pharmacology and Toxicology Journal is providing an essential service by publishing articles relating to the development aspects pertaining to the stages from discovery to the marketing of a new therapeutic agent.

While working in the area of scientific research for many years, I found that the application of statistics is not utilized to the extent which could add considerable value to the development of technology, evaluation of data, and interpretation of results for their intended use. The researcher has the responsibility for setting criteria, understanding the data variation, the level of significance and the extent to which the data can be applied. These responsibilities must be scientifically justified and using statistical analysis is an ideal approach for scientific justification. The EC Pharmacology and Toxicology Journal having a wide focus on the areas for publication will benefit readers by exposing them to multiple scientific disciplines.

Providing support to a variety of therapeutic agents and new chemical entities can create many challenges which can now be shared with other researchers through the format being provided by the EC Pharmacology and Toxicology Journal.

Volume 2 Issue 1 February 2016

© All rights reserved by Tom Catalano.