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The Role of Microscopy and Imaging in the Manufacture of Products for the Healthcare Industry

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The manufacture of products for the healthcare industry is continuously evolving as new and innovative products are developed with the aid of advancing production technologies to support their availability to the end user. Advancements in the understanding of patient needs along with breakthrough therapies and increasing patient populations due to access add another challenge to manufacturing strategies. In many cases the supply chain, that is, the components or active pharmaceutical ingredients constituting the product may have originated or have crossed multiple continents as part of the manufacturing process prior to final packaging at yet another geographical location. These products may then in turn be distributed back to the global marketplace whereby packaging science and controlled distribution practices become critical factors in the delivery of such products to the end user.

Despite the diversity of products, simple to complex, pharmaceutical or medical device, local or global production and/ or distribution, they all share a common requirement; patient safety. In the United States, the Food and Drug Administration (FDA), has established requirements known as the Code of Federal regulations (CFR) for how such products are to be manufactured to ensure the safety, integrity, sterility, purity, potency, and quality of the finished good [1], [2]. In conjunction with these requirements, the United States Pharmacopeia (USP) has established standards and acceptance criteria for manufacturers to demonstrate that products are produced in a manner that meets the expectations as defined in the CFR' [3]. The standards that have been accepted as official by USP are enforceable by the FDA for medicines manufactured and marketed in the United States.

Similarly, in other areas of the world the manufacture of product is governed by regional or international guidance that is further enforced by local, regional, or other geographical health ministry or government entity with authority.

As can be imagined, a multitude of opportunities exist for the implementation of various technologies in the manufacture of products for the healthcare industry and microscopy is no exception. In fact, microscopy has long been established as a discipline in this field and is continuously being employed across the entire life cycle of both pharmaceutical products and medical devices. Microscopy has also been established for use within the USP with subsequent adoption to other global compendia.

The presentation will explore the use of microscopy and imaging technologies as they are used to characterize product for research, development and continuous improvement opportunities. Furthermore, imaging technologies have also been making recent advancements into what have been traditionally "sensor" applications thus providing increased data sets for characterization purposes. The environments that these products are manufactured in must be of a high level of control including temperature, humidity, and the presence of viable (microorganisms) and non-viable (particulates) contamination. The use of microscopy and imaging are thus equally important in aiding the manufacturing environment as well as the technology utilized in making product.

Lastly, the use of microscopy and imaging technologies, along with their analytical counterparts, and the overlap with regulatory and health organizations will be discussed. This will include ensuring that not only is the appropriate data being collected, whether it is to demonstrate conformance or compliance, but that the data is integral and secure. This, along with the goals of both the manufacturer and regulator, will ensure that safe and efficacious product will always be delivered to the patient.

References:

[1] 21CFR210- Code of Federal Regulations, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, Title 21.
[2] 21CFR211- Code of Federal Regulations, Current Good Manufacturing Practice for Finished Pharmaceuticals, Title 21.
[3] United States Pharmacopeia, USP 41-NF 36, official May 1, 2018.

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