Project Name:

Deficiency letters trending leading to shaping the guidelines on Analytical Validation registration requirements:

Frequent deficiencies received from drug authorities are resulting in inefficiencies, not only at the applicant's side, but also at the authorities side. Frequent deficiencies will result in reworks and most importantly, will cause delays in getting approvals and therefore, delays in having high quality medicines available for patients in need. I have initiated a project at Hikma during which we have gathered the deficiencies received in 5 major countries in MENA during the past 3-5 years, conducted a thorough technical and statistical analysis, identified areas of the most frequently received deficiencies and the areas of critical impact on product quality. In Jordan, more than 40% of repetitive deficiencies were related to analytical validation, which is one of the critical milestones in JFDA for drug approval. Any re-work in this area means extra time, efforts and expenses (i.e. ordering new analytical items, reference standards, long lab hours …..etc). We worked internally with our analytical research department on upgrading our internal procedures by taking all repetitive points into consideration and in parallel, I worked closely with JAPM (Jordanian Association for Pharmaceutical Manufacturers) and with JFDA (Head of Validation) to address this area. That was a general issue encountered by all applicants (local industry and foreign).

Goal Achieved:

We had several workshops with JFDA and JAPM, some were targeting regulatory members in local pharmaceutical industries in Jordan and others targeting technical members (analytical research, quality control…). Thorough technical discussions of the detailed requirements, debate and assessment took place. This unique partnership and cooperation between JFDA and local industry was eventually coronated by the issuance of the "1st Guidelines on Analytical Validation" in September 2021, paving the way, not only for Hikma, but also for any applicant, for better understanding and alignment with authorities requirements and speedy approvals. We have started observing tangible reduction in the number and complexity of analytical validation deficiencies received from JFDA on Hikma registration files.