

SMART robotics in forced degradation.

When it comes to pharmaceutical products, quality is of the highest importance. Large investments are made to ensure raw materials are up to standard. Production processes are continuously monitored and final products are analyzed thoroughly (e.g. residual solvent analysis) to make sure the pharmaceutical end product meets the most stringent quality requirements.



However, once a high level is achieved, **maintaining the product quality** after production and packaging can be a challenge too. Loss in potency, appearance of toxic degradation products and unpredictable changes in overall product quality are undesirable. Extended API and formulation testing are a necessity during both the R&D and the production stages.

Indeed, changes in drug stability can risk patient safety or result in delivery of a lower than expected API dose. This will not only impair the efficiency of the treatment, but will impact product sales or, even worse, could harm the company's reputation.

Determining the purity profile and degradation behavior of a drug substance under various environmental conditions is typically done in a forced degradation setup. In these Accelerated Stability Assessment Programs (**ASAP-testing**) large numbers of samples, both API's and formulations, are subjected to increased chemical and/or physical stress for prolonged periods of time.

Duplicates taken at several time intervals up to 21 days will quickly result in large numbers of samples, flooding your lab in an irregular, project-based manner. In addition, these samples are unique, volume limited and can not be replaced easily. Retesting after human error for example really isn't a compelling option. So unfortunately, ASAP-testing is a very important but time consuming and resource intensive task often resulting in additional stress to your lab's routine workflow.



Smart automation is the logical step to take and SampleQ has developed a system specifically designed for ASAP-testing.

It can be used to prepare the long list of different solvent and buffer combinations (pH's) prior to the start of the stability study, but will also process all samples at the end of the ASAP-testing. Depending on your laboratory's setup, samples can be processed offline or online, coupled to your analytical systems. Off course all samples are tracked and traced with full logging capabilities. Using Smart Robotics in forced degradation will free your valued technical staff and researchers for other, more rewarding tasks.