NMR IN DRUG DEVELOPMENT: ROLE, CHALLENGES AND PROCESS CHEMISTRY SUSTAINABILITY

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Solution NMR plays a key role in the Pharmaceutical Research area as a powerfull tool for Identity testing and structural elucidation. Active Pharmaceutical Ingredient (API) synthesis requires process optimization to meet ICH requirements and reach sustainability. In this route scouting phase the generation of analytical information and specifically of NMR data is essential. Meanwhile during the GMP manufacturing stage, NMR applications range from materials identity test to full characterization for regulatory documentation.

In the recent years, quantitative NMR (qNMR) has been recognized as a powerful tool, alternative or orthogonal to other techniques. The application of qNMR can provide significant contribution in the process chemistry sustainability.

The Green Chemistry concept [1] can be defined as the "design of chemical products and processes to reduce or eliminate the use and generation of hazardous substances" and has been increasingly used in chemistry and pharmaceutical industries, by application of its twelve principles, which ultimately allow to both decrease the environmental impact and reduce the economic costs. The eleventh principle of the Green Chemistry [2] is about real-time analysis for pollution prevention, and shows how an analytical technique, such as NMR, can contribute to reduce time, costs and pollution in an early-phase Active Pharmaceutical Ingredient's (API) manufacturing process.

For its low environmental impact and robustness NMR spectroscopy is a useful and low time-consuming technique to monitor scale-up reactions for both qualitative and quantitative purposes.

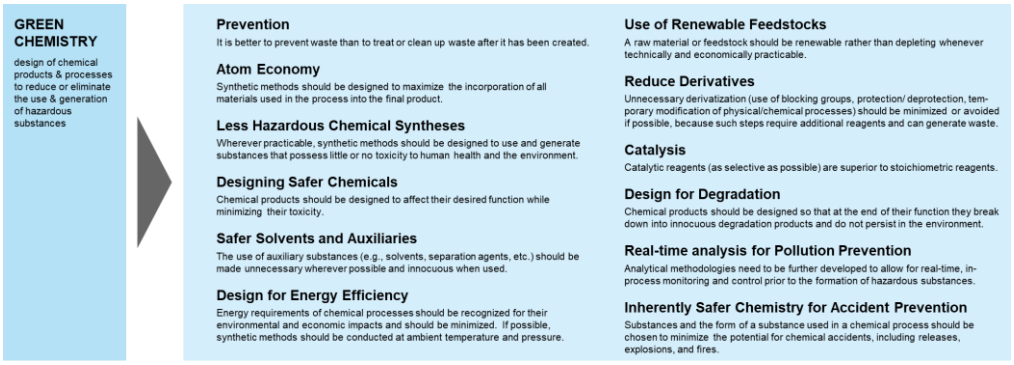

Figure 1. The twelve principles of Green chemistry.

REFERENCES

[1] P. T. Anastas, J.C. Warner, *Green Chemistry: Theory and Practice*, New York, Oxford University Press Inc., **1998**.

[2] P. T. Anastas, *Crit. Rev. Anal. Chem.* **1999**, *29*, 167–175.