

Plxsur's Regulatory and Science Core Principles

"Maintain, Create and Capture New Value"

Regulatory

Horizon scanning

- Keep track of the ever-changing legislation in all the regions in which the company wishes to operate for both consumer and medical nicotine containing products.

Regulatory positioning

- Responsible for the presentation of registration documents to regulatory agencies and carry out all the subsequent negotiations necessary to obtain and maintain market authorisation for the products concerned.

Market positioning

- Establish the filing strategy and advise on the most suitable route for filing new products.
- Develop and maintain product information on all nicotine consumer products.
- Support any product development.

Quality by design

- Provide strategic and technical input to product innovation, manufacturing and QC etc.
- Develop a robust product process which ultimately reduces the regulatory burden of pre and post-authorisation submissions.

Engagement (connect early and often)

- Conduct internal education workshops
- Prepare briefing documents for scientific advise meetings with MHRA, FDA etc.
- Attend and lead scientific advice meetings.
- Establish/maintain good working relationship with appropriate authorities.
- Establish a network of Key Opinion Leaders for support and advice.

Strategic and technical

- Provide regulatory and technical guidance for the submission and maintenance of TPD notifications in the EU and UK (equivalent).
- Provide equivalent support for rest-of-world markets as appropriate (e.g. PMTA in USA).

Science

Science and evidence

- Curate and provide data rich evidence to support regulatory submissions and market strategies.

Analytical science

- Analytical testing strategy for regulatory submissions, method development and data analytics.

Analytical testing

- End-to-end management of analytical testing from sample development to result interpretation and technical 3rd party management.

Product characterisation

- Foundation for all formulation and process development.
- Use appropriate scientific data sources and analyses to understand the behaviours of the product and impact of the different components as they relate to Tobacco Harm Reduction.

Pioneer research

- Conduct appropriate research (Primary and Secondary) to further knowledge within the area of Tobacco Harm reduction, Nicotine Replacement therapy etc, in the interest of public health, whilst supporting the pace of change in technology and regulation across EU, UK, US and ROW.