hallanalytical

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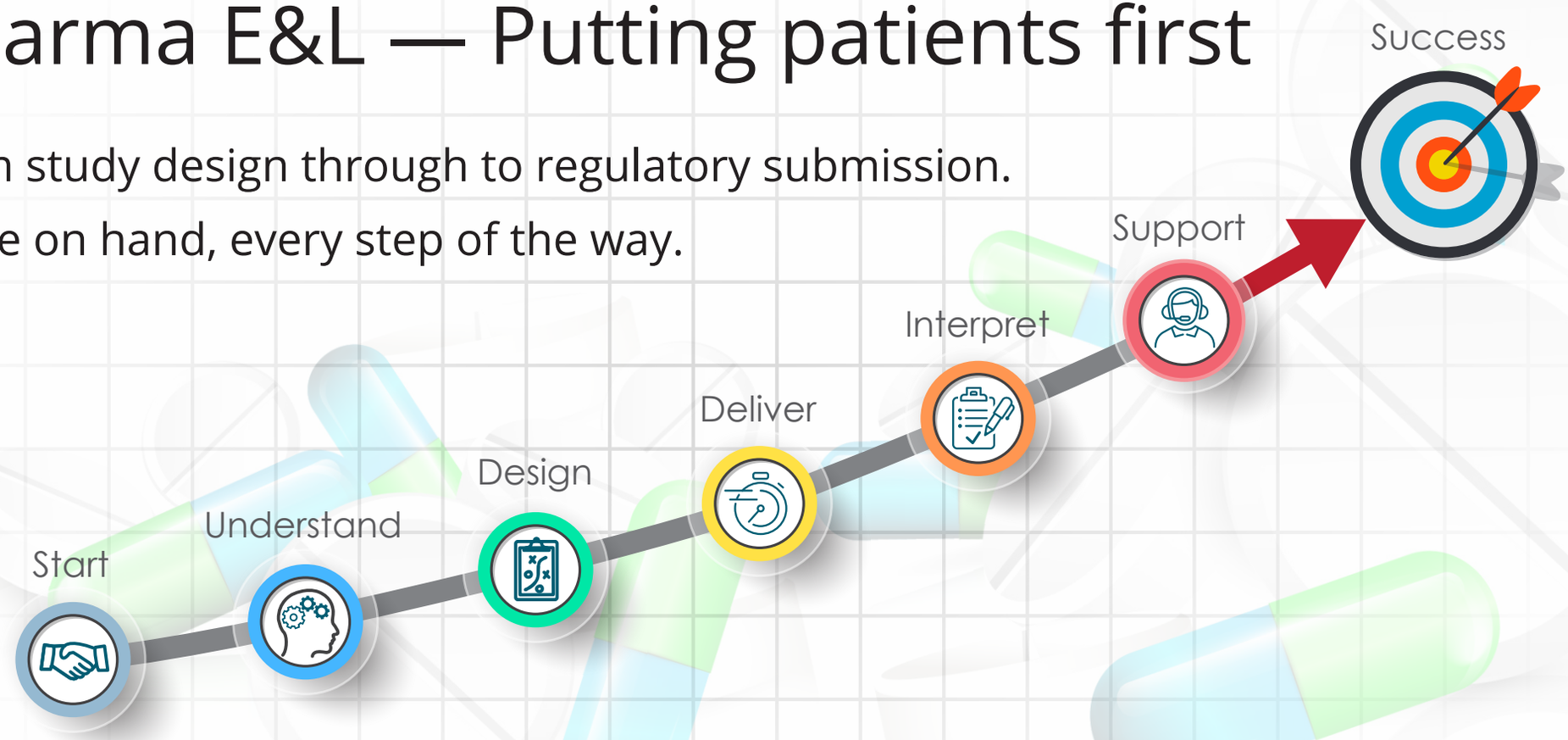
Pharma E&L — Putting patients first

From study design through to regulatory submission.

We're on hand, every step of the way.



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Potentially toxic compounds and reactive species can leach from materials used during the manufacture, storage and delivery of a drug product. The safety, efficacy or quality of the drug must not be affected by these compounds, and failure to properly investigate and control leachable compounds may result in life-threatening consequences.

E&L testing is complex and requires a great deal of experience and skill to properly assess risk, design appropriate studies and interpret data. Experience with testing a wide range of materials and products using a variety of analytical techniques is crucial if all of the extractable and leachable species are to be identified.

Situated in Manchester UK, the 'Home of Mass Spectrometry', Hall Analytical is a highly experienced and consultative testing partner, supporting E&L assessment every step of the way—from risk assessment and study design through to regulatory submission and beyond. We report findings in a format of your choosing and help you interpret the data with on-going support for as long as you need it.

A Dedicated Single Point of Contact

Hall Analytical clients receive a dedicated expert to assist with all queries. These are some of the ways that we can help.

Seamless communication
Client managers can quickly address commercial, administrative and scientific questions, either directly or through delegation.

No need to re-explain
Zero-risk from miscommunication, preventing the need to repeat questions and requests.

Logistical support
Sample shipping logistics can be time-consuming and delays are rife if these workflows are not kept on top of. To reduce lead times, our client managers will arrange samples, shipping, and paperwork on your behalf

Develop an understanding

Working alongside our clients, we use our extensive experience to ensure that your testing is fit for purpose—determining the type of sample extraction, testing, reporting thresholds and reporting format that you need. What's more, our analysis is delivered within an industry-leading timeframe (typically within 6 weeks).

Expertise & experience

Having spent over 20 years performing thousands of tests on a range of products, our team is well placed to guide you through the various testing approaches to ensure that your materials are assessed in the most appropriate way to assess patient risk.

Risk assessment

Based on our extensive experience working with material/component suppliers, medical device and pharmaceutical/biopharmaceutical manufactures. We can undertake a proven risk assessment exercise to evaluate the need for analytical testing and suggest the appropriate extraction conditions and analytical tests.

Design the appropriate testing

Working together, we will design the method best suited to your analytical needs.

Run the right tests

Ensure quality by selecting the appropriate methodologies for analytical testing. Produce the right data to answer the specific requirements or to support business-critical decisions.

No unnecessary testing

Sometimes, testing is not appropriate to evaluate risk. This necessitates a risk assessment to industry standards in order to determine the most effective way of qualifying risk.

Meet regulatory requirements

If we have determined that testing is necessary, we will guide you through the various guidelines through e.g. USP / BPOG / ISO testing approaches or design bespoke studies to meet regulatory expectations and to ensure you are assessing patient risk in the most appropriate way.

On-time delivery of test reports

We are committed to providing analysis on time and, critically, in the format of your choice.

Time sensitive analysis

There are many circumstances in which testing is time critical. We typically deliver in 4-8 weeks (unrivalled within the industry) from project brief to final report. This helps with:

- Manufacturing problems or last-minute changes
- Issues with materials or products
- Time-critical regulatory submissions or queries
- Changes within the supply chain

Reports written in your format

E&L testing is complex, and the data can be difficult to discern—so we always provide it in your format. If you don't already have a template, we can provide something appropriate. This is critical as it means:

- Fewer transcription errors
- Reduced administrative burden
- A comprehensive understanding of business-critical data across your organisation

Responsive

Outsourcing analysis can impact your timelines and decision-making if your partner is not communicative. A focus on clients is embedded in our working culture. We guarantee:

- To address or acknowledge all enquiries on the same day
- Quick answers to your questions
- Peace of mind
- Continuous updates on progress, interim reporting and calls when required

Helping you understand the results

What use is data if you can't make sense of it?
We will aid you in this process, ensuring that you have the understanding to inform business-critical decisions.

With our extensive E&L testing experience, we have worked with a variety of dose forms and all the most common materials, building an industry leading database of extractable and leachable compounds. Our testing will deliver:

- Fewer unknowns that require additional resources to identify
- Best insight into the choice of your materials before your bill of materials is finalised
- Better understanding of the classes of materials in the rare instances where compounds not previously characterised are detected

Information is so much more than data

We work with our clients to help them interpret the data in context—ensuring that we effectively support business-critical decisions and regulatory submissions.

This includes:

- Evaluation of risk in the context of your product, process or container closure/delivery system
- Toxicological risk
- Interpretation of data

In short – We'll handle the data.
You'll have the product information you need for critical business decisions.

Ongoing Support

Following analysis, we are committed to ensuring you have all the support you need, regardless of timescale.

Peace of mind

Clients often have questions regarding their testing long after the analysis occurred. To us, this is all part of the service. We're happy to support you through any matters arising from our testing at any time in the future.

Regulatory reports/dossiers

Our studies are designed to maximise the chance of regulatory approval. However, should regulators return with questions on the testing or interpretation, we will support you until they are satisfied.

If required, we can liaise with the regulators to seek clarifications, or to help justify testing approaches and conclusions.

Client Success

Our success relies on your success. We're on-hand, every step of the way.

Hall Analytical Laboratories can provide the following services to ensure your success in E&L analysis for risk evaluation and management:

- Risk assessment
- E&L study design
- Logistical expertise
- Stability storage
- Analytical testing protocol design
- Analytical testing (UV / IR / HPLC(HRMS) / GC(HRMS) / TOC / ICP-MS)
- Toxicological assessment
- Regulatory submission writing

You will be entirely confident in the information we obtain together. That is our value proposition to you.