SMITHERS
ACCURATE DATA • ON TIME • HIGH TOUCH

Pharmaceutical and Medical Device Chemical Analysis

Smithers supports the pharmaceutical and medical device industry with expert advice, troubleshooting and testing services within our GMP and FDA registered laboratories.

Our expertise encompasses medical devices, primary container closure systems, secondary packaging components, single use processing systems as well as excipient and drug substance and drug product analysis and impurities.

Extractables and Leachables (E&L) Testing / Chemical Characterization

We provide comprehensive E&L studies to evaluate risks to patients from materials of construction of drug product contact materials and medical devices. Products typically studied include:

- Orally Inhaled nasal drug products
- Parenteral products
- Ophthalmic products
- Bioprocessing - Single Use Technologies
- Medical devices
- Combination products

Smithers' extractables and leachables (E&L) and biocompatibility testing programs are designed to fulfil global regulatory requirements. Our test programs following global best practice including: USP<665>, USP <1663>, USP <1664>, USP <1664.1>, PQRI, FDA, EMA, ISO 10993 etc. Our laboratory techniques included: High Resolution (HR) LC-MS/UV, GC-MS, ICP-MS, Headspace GC-MS and other complimentary techniques such as FTIR, TOC, pH, UV/Vis, conductivity.

Laboratory work for E&L testing is controlled by a mutually agreed Study Plan and a quality reviewed cGMP report is issued at the end of the study. Our continuous improvement program ensures that our in-house methods provide the maximum chance for the identification of E&L. Leachables method validation follow ICH Q2 (R2) and to meet client specific requirements.

Medical Device & Pharmaceutical Product Expertise from Smithers

Smithers helps medical device and pharmaceutical product manufacturers bring innovative and highly effective products to market with world-class expertise and extensive, independent testing capabilities at accredited facilities in the UK and USA.

Our experienced team provides advice, guidance and recommendations as well as delivering test data to help you demonstrate compliance to regulatory guidance and specifications set out by the FDA, EMA, MHRA, USP, ASTM and ISO.

We can assist throughout your product development.

LIFE SCIENCES

Single Use Technologies (SUT) – USP <665>, BPOG

We perform E&L testing of SUT including:

- Filters
- Tubing
- Connectors
- Gaskets
- Valves
- Process containers (bags)
- Whole systems simulations

Within our cGMP facility, we have temperature-controlled chambers of various sizes to accommodate small and large systems. Smithers can tailor testing to your needs and conduct studies following BPOG, USP <665> and other industry standards.

Quality

Our laboratories are ISO 17025 accredited, FDA registered and inspected and operate a wide range of analytical equipment and techniques to examine the chemical properties of polymeric materials, excipients and API.

Packaging Materials Pharmacopoeia Testing – USP and Ph.Eur. testing

We support European Pharmacopoeia (Ph.Eur.) and United States Pharmacopoeia (USP) testing for container closure, packaging and material testing. Including: USP <661.1>, USP <661.2>, USP <381>, USP <232> Ph.Eur. Sections 3.1 and 3.2

Drug Substance and Drug Product Assays

We support drug product assay and impurity assays for R&D and batch release under cGMP. As well as supporting standard methods, we have expertise developing methods for challenging compounds that require high resolution mass spectrometry methods.

At Smithers our experts have the industry knowledge and laboratory resources to develop and validate to satisfy regulatory requirements.

Elemental Analysis USP, <232>, USP <233>, Ph.Eur 2.4.20, ICH Q3D

Smithers can support metals analysis following industry best practice for R&D, batch release and impurity investigations. Methods can be validated following industry practice and where required utilize digestion methods such as microwave.

Troubleshooting Impurities and Contamination Identification

Smithers offer immediate support if things have not gone to plan. Utilizing analytical knowhow and state of the art analytical equipment we can help you identify and root cause impurities, be it drug related, material related or unknown. Our first-class laboratory provides confidential, high-quality data and can offer an expedited service when required.

Risk Assessment and Consultancy

Our expertise extends beyond cutting edge E&L laboratory testing, our heritage is material science, giving us unique insight into how polymers potentially interact. We offer expert guidance in analysis, E&L program design, and material risk assessment, adhering to USP <1661> and USP <1665> standards.

Associated Services

- Device characterization and verification
- Healthcare product and package validation including shelf-life studies, transport simulations and integrity testing
- Material selection, processing and manufacturing, material testing, consultancy and training

Laboratory Testing and Analysis of:

- Extractables and Leachables (E&L)
- Single Use Technologies (SUT)
- Medical Devices and combination products
- Chemical Characterization
- Impurities and batch testing

Speak to Our Experts

Michael Creese
Extractables & Leachables, Chemical Analysis
mcreese@smithers.com
+44 (0) 1939 250383

Sean Thomson
Commercial Director
sthomson@smithers.com
+33 (0) 660 125 828

Alison Schweda
Americas
Business Development Manager
aschweda@smithers.com
+1 330 607 4699

Brian DeRhen
Ireland & Scandinavia
Business Development Manager
bderhen@smithers.com
+44 (0) 7739 979375

Mike Bachmann
UK, Germany, Netherlands & Austria
Business Development Manager
mbachmann@smithers.com
+44 (0)7788 201 212

Medical Device Testing Division
info@smithers.com
www.smithers.com

Akron, Ohio, U.S.A.
Tel: +1 330 762 7441

Shawbury, U.K.
Tel: +44 (0) 1939 250383

Leatherhead, U.K.
Tel: +44 (0) 1372 802000

SMITHERS
ACCURATE DATA • ON TIME • HIGH TOUCH