PHARMACEUTICAL NEWSLETTER Q2 2019

Hello to our customers and contacts in the Pharmaceutical industry.

Welcome to the latest edition of our quarterly newsletter.

Last year, APP and IPT had a strong performance in the Pharmaceutical sector, particularly in container closure integrity testing (CCIT).

We also noted a rise in contract packaging organisations, as well as the need for diversity of scale in packaging and package testing.

Brexit is certainly a topic of interest. In preparation, we are working with our suppliers and partners in logistics to try and minimise any disruption to business.

Closer to home, APP in the UK and IPT in Ireland became one single brand identity this year - IPP Ltd. This will further integrate the UK and Irish teams resulting in a clear brand and stronger customer support.

We look forward to working with you and supporting your business in the coming year.

Happy reading!

Jack Daly
Managing Director

Mobile UK - +44 7802 452058
Mobile IRE - +353 86 8314643
Email: jdaly@ippgroupltd.com

ANGLO PRODUCTION PROCESSES (APP) LTD AND INDUSTRIAL POWER TOOLS (IPT) LTD

BECOME ONE BRAND

INDUSTRIAL PRODUCTION PROCESSES (IPP) LTD

From 1 March 2019,

UK based Anglo Production Processes (APP) Ltd and Irish limited company, Industrial Power Tools (IPT) Ltd will operate under one brand, Industrial Production Processes (IPP) Ltd.

IPP unites our distribution business in the electronics, pharmaceutical and medical device sectors across Ireland and the UK to improve the efficiency of our customer service and build brand awareness in both territories.

There is no action required by our APP customers. All payments will remain the same at APP.

IPT Ltd is trading as IPP until Q4 of this year. All payments will remain the same for IPT customers and suppliers. In Q4, the company will change to IPP Ltd. Customers and suppliers will be advised of pertinent information well in advance of this date.

For more information, please contact your local sales manager or email Laura Sheahan at lsheahan@ippgroupltd.com

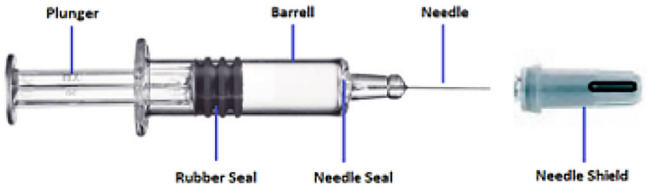
About IPP:

With over 40 years' experience, IPP (formerly APP Ltd in the UK and IPT Ltd trading as IPP in Ireland) is a technical distributor of manufacturing equipment to the electronics, pharmaceutical and medical device sectors across the UK and Ireland.

LEAK DETECTION OF PRE-FILLED SYRINGES

Recent years have seen a significant rise in the use of pre-filled syringes (PFS) as a containment solution for pharmaceutical products. This trend is expected to accelerate over the coming decades. For the pharmaceutical company, the advantages of prefilled syringes are minimizing drug waste and increasing product life span. For healthcare workers, prefilled syringes are recognized as an efficient, reliable and convenient method for drug administration. Furthermore, many injectables can be self-administered without the concern of complete transfer from a vial. This gives rise to a safe and efficient option for patients requiring long-term pharmaceutical therapies.

However, from an inspection perspective, the PFS gives rise to a new set of criteria to be considered. With the method of delivery being as important as the product, we see an ever increasing overlap between the world of medical device and pharmaceutical manufacture. In the field of container closure integrity inspection (CCIT), prefilled syringes offer more complexity when compared with the traditional vial. For a PFS, there are more pathways and possibilities for a containment breach to occur as we consider the barrel, needle, plunger and seal ring.



A key consideration when considering the PFS for inspection is the distinction between quality issues and container integrity issues. For example, the needle could be slightly bent within the shield but may not have pierced the cap. In this case the PFS would clearly fail on quality but from a container perspective, there may not be a breach through to the liquid inside. Another frequent example on this is the rubber seal on the plunger. Typically this has ribs or fins which act as container integrity seals. If liquid has passed the inner fin but not the middle or outer, again this would be a quality fail but the closure integrity may well still be intact. This distinction means that it is important that we consider CCIT as a subset of overall package quality.

From a CCIT perspective, one of the best technology solutions to use for PFSs is High Voltage Leak Detection (HVLD). HVLD is non-destructive which is an important consideration when you want a test method that is both 100% and repeatable. HVLD is also deterministic in that it offers both historical and real time data that can be assessed against pass/fail criteria, thus eliminating the subjectivity of human visual inspection.

HVLD works by briefly applying a voltage across the syringe. In the event that the PFS has a containment breach through to the liquid, there will be a significant change to the resistance value between the test electrodes. This creates a recordable change in the value of current/voltage in the test device.

However, significantly, where HVLD works particularly well for pre-filled syringes is that it is able to detect failures from multiple different sources by moving either the test electrode or the PFS to focus on a particular area.

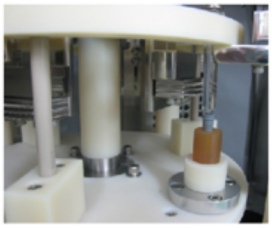
- If the glass/plastic barrel is cracked or has a pinhole, this will be detected easily.
- If the liquid has leaked passed the rubber seal on the plunger, this can be detected by bringing an electrode close by. However, if the defect has not breached all of the fins there may not be a pathway from the liquid through to the environment, and so this may need to picked up on a quality inspection rather than a container closure integrity test.
- If the needle seal is compromised, any leak path through to the inside of the needle can be detected.

The needle creates an interesting situation for CCIT. If the needle bends and pierces the inner soft shield but does not pierce the outer cap, then two issues here need to addressed. Firstly, this bending of the needle may result in damage to the needle seal inside the barrel. If a leak occurs here, this can be detected by HVLD. But also, a HVLD system may be able to detect the needle having pierced only the inner soft cap. Many PFS hard caps now have windows or holes. In this instance, the needle will offer a low resistance path due to the repositioning of the metal. This allows HVLD to be used to detect needle bending for many PFS types, depending on the design of the hard cap.
Possible solutions when looking at HVLD as a solution for PFS testing include:

pti Packaging Technologies and Inspection, LLC

The PTI E-Scan655 offers offline HVLD testing for prefilled syringes.

Nikka



The Nikka Densok HDT offers inline HVLD testing for prefilled syringes.

To find out more, or arrange an appointment with your local Technical Sales Manager, email Laura Sheahan at lsheahan@ippgroupltd.com

HOW AN EFFECTIVE PROGRAMME OF SERIALISATION CAN BE IMPLEMENTED SUCCESSFULLY

Ethypharm (formerly Martindale Pharma) in Romford, UK, demonstrates how an effective programme of serialisation, i.e. the traceability of medicines, can successfully be put into practice in today's pharmaceutical industry.

Challenge

Protection against falsified medicines has become the leading issue for the pharmaceutical industry in recent years. According to EU Regulation 2016/161, all pharmaceutical packaging must be serialised and fitted with an anti-tampering device from February 2019.

Solution

It was with this end goal in mind that the company joined forces with METTLER TOLEDO(MT)/PCE and their UK partners IPP to deliver a solution that was robust, flexible and would be suitable for the range of automated and manual lines that they had in Romford.

The challenge was to find a partner with a range of options that could integrate to both high and low volume lines, had standalone equipment and also kits that could be integrated into their existing cartoners and casepackers.

The investment decision followed an external benchmarking process, in which technology from various providers was considered. The key factor in favour of IPP and PCE was the local support that could be provided by IPP, coupled with the knowledge that MT/PCE is a world class solution used by many of the large global players.

Results

The plant went live in January 2019 and all lines are now up and running. There were some initial teething problems but the IPP Engineers were on hand to smooth these over. All five lines are now running successfully with additional lines planned for 2019.

Customer feedback

'We're very satisfied with our choice of partner and the good working relationship we have developed with IPP'.
Ethypharm's Head of Technical Operations & Engineering Cliff Easter

To find out more, or arrange an appointment with your local Technical Sales Manager, email Laura Sheahan at lsheahan@ippgroupltd.com

SHARP ANNOUNCED £9 MILLION INVESTMENT IN EUROPEAN CLINICAL SERVICES CENTRE OF EXCELLENCE

Sharp Clinical Services, part of UDG Healthcare plc, has announced a £9 million investment to fund a new multiple-phase pharmaceutical manufacturing, packaging and distribution facility in Wales. The investment, which also includes £500,000 from the Welsh Government, will enable the company to satisfy increased demand for Phase III clinical and commercial services.

The build of the state-of-the-art unit will replace the company's existing site in Crickhowell, Powys and will triple Sharp's clinical service capacity for the global pharmaceutical, biotech and clinical research sectors.

By developing its manufacturing and analytical capabilities, adding automated bottling, blistering and serialisation, as well as IRT services for clinical trial management, Sharp will be able to offer full service support for larger global clinical studies from this new European clinical centre of excellence.

As part of the expansion, Sharp, part of UDG Healthcare plc, purchased a Pentapack machine for the new £9 million multiple-phase pharmaceutical manufacturing, packaging and distribution facility in Wales.

The Pentapack BP 1540 opens up a new level of blistering.

- No special training is required
- Quick tool change
- Very easy to use and very low maintenance
- Manual and automatic filling
- Maximum 8 stations
- Maximum foil width 160mm

Final blister:

- Straight Knife
- Round Corner Die Punch

Vision inspection:

- Inspect Product Placement
- Integrity
- Colour
- Length feeding area: ± 1500mm

NEWS

IPP brings Super Dry® Totech's dry cabinets to Ireland

IPP Ireland became the Irish distributor of Super Dry® Totech. Super Dry® Totech began nearly a decade ago as a distribution and technical support channel for ultra-low humidity dry cabinets with patented Zeolite technology.

Rapid growth was fuelled by European RoHS legislation that magnified the need to carefully control product failures caused by moisture sensitive devices (MSDs). Since then, Super Dry® Totech has become an independent design and manufacturing organization serving global markets with leading edge MSD solutions.

Unlike clay or silica, Super Dry® Totech's patented technology uses a crystal known as Zeolite. A molecular sieve, water molecules are literally sifted from the air inside the cabinet. The desiccant is never touched by operators, and it never needs replacing.

Managing Director of IPP Jack Daly is pleased to partner with Super Dry® Totech, a member of the ASYS Group, "Having partnered with ASYS for many years, we are delighted to grow our relationship and distribute Super Dry® Totech's ultra-low humidity dry cabinets with patented Zeolite technology in Ireland."

Super Dry® ToTech's Managing Director Jos Brehler is excited to bring its dry cabinets to Ireland through its IPP partnership, "Our development efforts have produced new levels of drying performance as well as environmentally responsible, industry-leading solutions such as our XSD & XSDB series."

For more, please visit our website at
www.ippgroupltd.com

EVENTS

Making Pharmaceuticals, 30 April to 1 May 2019, Ricoh Arena, Coventry, UK

Join Industrial Production Processes (IPP) Ltd at Making Pharma 2019, stand 200.

We will have live demos on a range of packaging equipment, packaging inspection equipment and serialisation equipment.

PTI - Packaging Technologies & Inspection's Sales and Applications Engineer, Jason Sciarabba, will present on the *Advances in Deterministic Parenteral Container Closure Integrity* on Wednesday 1 May at 2.40pm.

Register for free today to secure your place at www.makingpharma.com

MedTech Innovation Expo, 15 and 16 May 2019, NEC Birmingham, UK

IPP will be exhibiting at MedTech Innovation Expo 2019, stand D3.

We will have live demos on a range of packaging equipment, packaging testing equipment, and manufacturing and automation equipment.

IPP's Director of Life Sciences Donal Harrington will present on *Stent Package Integrity - Regulatory Shifts and the Technological Drivers* on Wednesday 15 May at 3.20pm.

Register for free today to secure your place at
www.med-techexpo.com

IPP IRELAND
18D Euro Business Park, Little Island,
Cork T45 DP80, Ireland
Tel: +353 21 423 2233 | Email: sales@ippgroupltd.com
www.ippgroupltd.com

IPP UK
Saxon Business Park, Hanbury Road,
Stoke Prior, Bromsgrove B60 4AD, UK
Tel: +44 1527 578 972 | Email: sales@ippgroupltd.com
www.ippgroupltd.com