

in this second issue...

Welcome Pharma Focus Readers

Welcome to the second edition of Pharma Focus!

In this edition we discuss the impact of legislation on cleaning methodology. How IWT Pharma can support our partners develop washing solutions to ensure their cleaning routines prevent contamination, are repeatable, controlled and validated. We believe automation of cleaning procedures will play a big part in the future of washing. Read more about this one page 1.

Our regular feature 'Application Focus' looks at cleaning solutions for your applications. In this edition we investigate washing solutions for hoses, discover why the W200 series is the perfect washing solution for this application.

Our Breaking News feature looks at one companies drive for a repeatable and validated washing solution and how IWT Pharma provided them with the ultimate solution. Find out more on page 3.

If you would like to find out more about any of the topics we have discussed in this newsletter please don't hesitate to contact me on richardc@tecnplastuk.com.

Happy Reading!

Richard

Richard Clarke



}01 Legislation Enforcement



}03 Breaking News



}04 Application Focus



How is legislation enforcement effecting you?

What is the influence of legislation enforcement around cGMP (Good Manufacturing Practice) and just what is its effect on our partners understanding of washing methodology and the need for automated washing solutions? Here at IWT Pharma we believe our partners are beginning to discuss this in more depth. It is certainly a topic which regulatory bodies are becoming more and more focused on.

With new legislation enforcement on the agenda, industry must now demonstrate how a hand washing SOP (Stand Operating Procedure) can provide safety to its technicians and cleaning specialists, whilst also delivering a fully traceable and repeatable cleaning process. We believe that automation will play a key part in future washing procedures especially when considering the challenges of a modern wash room environment.

So, what can the introduction of an automated washing solution offer? How will it ensure future alignment to legislation? And on what deliverables will it exceed?

Automation will...

- Prevent and help eliminate product contamination in manufacture
- Prevent cross-contamination among different batches or different products/processes
- Ensure quality, effectiveness and safety of the product
- It is a reproducible, controlled and validated process
- Protect users from the harsh effects of chemical exposure as commonly utilised in the cleaning of contaminated manufacturing equipment

As a manufacturer to the Pharmaceutical Industry of Washing Systems, IWT Pharma look towards the guidelines and standards, as almost a rule book, of how we can support our industry partners become better equipped to solve these legislation challenges.

Codes and frameworks are designed to offer a clear roadmap for manufactures. The Tecniplast Group are already fully skilled to support all legislative requirements as they have a wealth of experience in the Life Science industry including the Biomedical field. Our Biopharma industry follows the Code of Federal Regulations (CFR) Title 21, Parts 211 and 212 of the US FDA.

IWT Pharma washers are fully compliant with Paragraph D in part 211: five sections concerning equipment and machinery, including washers.

- Sec. 211.63: equipment design, size and location
- Sec. 211.65: equipment construction
- Sec. 211.67: equipment cleaning and maintenance
- Sec. 211.68: automatic, mechanical and electronic equipment, size and location
- Sec. 211.72: filters

When we think about the need to provide a controlled and validated solution, Document 21 CFR part

11 is also essential, as it deals with the use of electronic technology. It is divided into two main sections: electronic registers and electronic signatures.

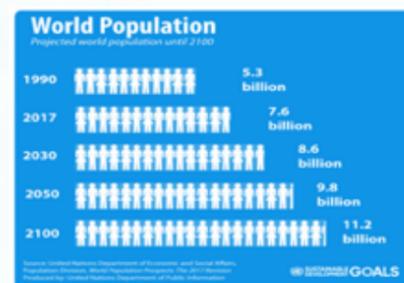
The FDA regulation on equipment design and manufacturing must also be supplemented by compliance with the following guidelines:

- International Society for Pharmaceutical Engineering (ISPE Baseline Guides)
- Good Automated Manufacturing Practice (GAMP 5)
- Standards for washing and disinfection equipment (ISO 15883-1:2006 and BS EN ISO 15883-2:2009)
- Standard for aseptic installation: American Society of Mechanical Engineers: Bioprocessing Equipment (ASME-BPE)

With this legislation and key objectives in mind, we believe there will be a steady departure from the historical method of Hand Washing and a drive towards cleaning within a controlled environment (Parts Washer or BIN/IBC Washers). This will be a step change within the Industry! However, IWT Pharma have the skills and expertise to ensure your washing methodology is fully compliant.

What is certain is with an ever-increasing global population

and the average life expectancy steadily increasing the need for pharmaceuticals will continue to grow on an ever-expanding consumer marketplace.



The big question for the Pharmaceutical manufacturing industry is now how much longer they can afford to not make the correct investments towards a more automated and controlled cleaning process in order to safeguard their respective positions as suppliers to this vital industry.

If you would like to find out more about Washing Automation, please contact Business Development Manager Richard Clarke on 0345 050 4556 or email him at richardc@tecniplastuk.com.

BREAKING NEWS



Rise of the Machine

Manufacturers within the Pharmaceutical markets are becoming more and more aware of the strict hygiene standards that are being enforced throughout all global markets and as a direct result, hand washing is quickly becoming an outlawed practise. The main reason for this change in cleaning practise is due to the need to offer a fully repeatable process that ensures total component part coverage with the wash waters at an accurate and controlled temperature together with total control around cleaning chemicals (if needed).



To manage this by hand is a real challenge, imagine the variables involved? Now factor in a business that entrusts this critical process to multiple colleagues spread out over 2-3 shifts a day and over a 6-day working week! It would be almost impossible to provide any level of repeatability and so it is for this reason that the demand by regulatory bodies such as the FDA are insisting that Pharmaceutical manufactures turn towards automation as the only method for cleaning of product contact components.

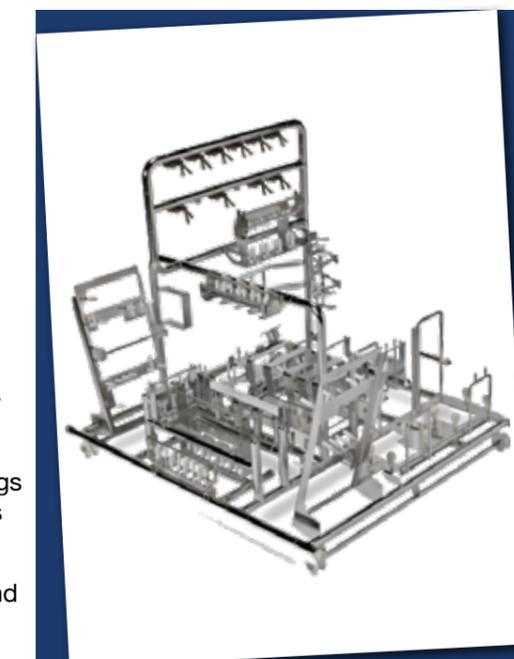
So, in early 2019 Tecniplast UK realised the success of the largest singular order with an award of 4 washing systems!

The order consisted of:

- 2 off W200 series Part Washers
- 2 off 2CLEAN Bin/Part Washers
- 6 off Customised Loading Wash Racks

The order was secured through our companies desire to offer a true customer focused solution towards the wash racks and the support offered with helping our new partner move away from the historic methods of equipment cleaning by hand to a fully automated system. The key in this comes from creation of fully optimised loading racks and a high level of customer engagement via our dedicated Project Management team. Also being available to attend routine site meetings with other vendors involved with the massive project is a key towards ensuring total customer satisfaction a timely project completion.

FAT's will have been completed within the programmes time frame and we look forward to seeing the first units arrive in our newly extended facilities before Christmas.



APPLICATION FOCUS



Do you need to clean hoses that have...

- Multi end connections
- Varied internal hose diameter sizes ranging from 15mm to 75mm
- A range of hose lengths up to 5mtr
- Different types of material of the hose construction that can limit flex performance
- Surface finishes (both internally and externally) that can impact cleaning greatly.

If so IWT Pharma have the perfect cleaning solution: W200 - GMP Contact Part Washer...

This washer has a large internal chamber capacity to allow ergonomic placement of multiple hoses per washing cycle. A full utility circuit control to ensure excellent wash water coverage performance to all hose surfaces both internally and externally.

We offer a range of multiple connection options to ensure interchange abilities to all conventional hygienic grade end connections. The W200 Series has full control towards both internal and external drying function. We also offer interchangeable racking designs to allow for total customisation if needed.

The W200 Series is totally compliant cGMP Contact Part Washer designed with the latest in design and construction technology.

If you would like more information about the W200 Series Washer call us on 0345 050 4556.



PPMA Show 2019



In October we were delighted to attend the PPMA Show at the Birmingham NEC.

It was our first time at the exhibition and washing experts Richard Clarke and Luca Fumagalli were on stand to introduce delegates to the **IWT Cleaning Excellence world**.

On the stand you could discover the latest in mobile washing technology; the **MLine!** This is the ideal washing system for the product contact parts of any pharmaceutical IBC, drum, preparation tank and bulk container in general, it is also suitable for a wide range of applications (CIP and COP).

Click the following link to see the MLine's powerful washing capabilities <https://www.youtube.com/watch?v=FtVHC37N8GA&t=32s>

During the show you could also learn more about the **2Clean** a combination cleaning solution that provides the user with an opportunity to manage both IBC/Bin application and a Small Parts Washer in one.

Joining us on our stand was ChargePoint who specialise in valves that contain and safely transfer sterile powders and liquids. The IWT Pharma IBC and Bin washing systems are designed to support the efficient cleaning of these market leading valves in our 2Clean and C-Line washing systems. We also were joined by scanning company 3DOR design who we use to ensure our bespoke baskets are designed to your specifications which in turn ensures our washing solutions are simply excellent.

The event was a great success! If you didn't get chance to see us there, we will see you at the Making Pharmaceutical Exhibitions in 2020!

For more information on all our products and services please visit our website www.iwtpharma.com

UPCOMING EVENTS

2020

Making Pharmaceutical

Ricoh Arena, Coventry



Making Pharmaceutical Ireland

Royal Dublin Society, Industries Hall



Why not visit us in Italy?

IWT Pharma has just made a multi-million pound investment in their manufacturing unit, why not join us in Italy so we can show you how we can make a difference!

For more information visit our website <https://www.iwtpharma.com/en/designedforyou.html> or call Richard Clarke on 0345 050 4556.