



INDIAN CLEANROOM LAUNDRY



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INTRODUCTION



Micronclean is the UK's leading cleanroom laundry supplier providing specialist workwear and cleanroom laundry services to companies in the pharma, healthcare, microelectronics, aerospace and semiconductor industries. With a 65% market share our ISO Class 4 and 6 laundries provide cleanroom clothing to all the large UK based pharmaceutical companies including Astra Zeneca, GSK, Mylan and Dr Reddy's.

As a UK based company Micronclean currently has a £32m turnover but our aspiration is to reach £100m by 2027, with growth from all sectors we operate in but the largest forecast will be in export consumables and in the soon-to-launch India Cleanroom Laundry business.

From initial research we found that despite India's large and rapidly growing pharmaceutical industry, there were no commercial cleanroom laundries; it was all served by in-house, on-premise laundries that were not compliant with regulatory requirements. As a result we felt that Micronclean could export our existing technology in a turn key format so that from day one of operation our cleanroom laundry customers could benefit from our 30 plus years of building and running GMP compliant laundries.

As a result, Micronclean have acquired a three-acre site at Vemagal to the North East of Bangalore. The design has now been completed and we are in the process of tendering the construction packages. The build is due to be operational in Q3 2019. Phase one will be for two cleanrooms with a total capacity of 80,000 garments per week. Phase two will double this capacity. From this base we will be able to offer a daily delivery service to the pharmaceutical hubs of Bangalore, Goa, Hyderabad, Pune and Vishakhapatnam

This brochure introduces the key features of a cleanroom laundry covering the layout and capability of the cleanroom laundry itself, the key features of the laundry rental service and illustrating Micronclean's tried and tested garment range developed from our years of experience working with UK cleanroom clients.

Simon Fry
Chairman
Micronclean





POTENTIAL CUSTOMER AREAS

TARGET SECTORS

The Micronclean Cleanroom Laundry in Bangalore will operate to cGMP Grade B / ISO 14644 class 5 standards and produce cleanroom garments suitable for use in sectors where biocontamination control is critical. Typical target sectors include the aseptic production of injectable pharmaceuticals, pharmaceutical tableting plants, other biotechnology products as well as semi-conductor production.

Typically, the standards required for these sectors can be summarised as the provision of cleanroom garments which are -

- Visually clean;
- Free from physical contamination;
- Processed to have a very low level of residual particulate contamination (compliant with Class A of ASTM F51-00 / Category I of IEST RP CC 003);
- If damaged, repaired to a standard compatible for cleanroom end-use and in line with customer requirements (where specified);
- Processed to have a very low bioburden;
- Produced in an environment designed to minimise physical, chemical and biological contamination and monitored for particulate and microbiological contamination to Grade B of the cGMP guidelines;
- Sterilised using autoclaves if required.





GARMENT RENTAL MODEL



GARMENT RENTAL MODEL BENEFITS

CLEAN WORKWEAR ALWAYS AVAILABLE

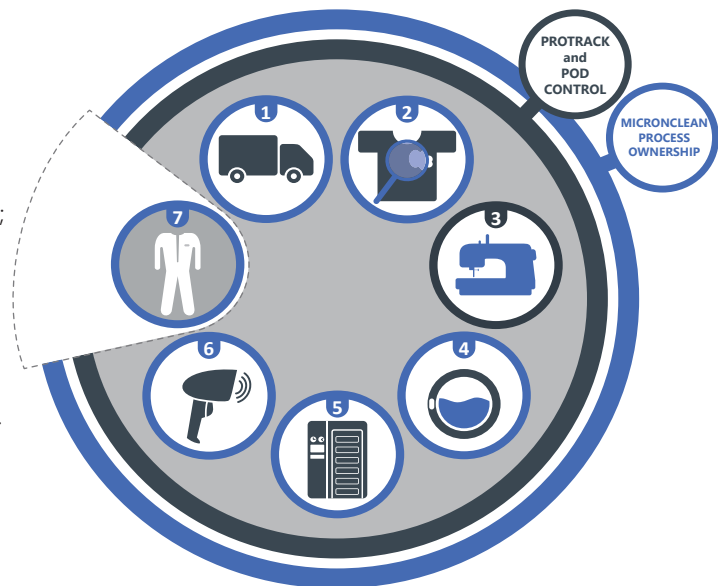
With our cleanroom laundry service, you can ensure that all your employees always have clean compliant garments available as we will deliver the garments on our fleet of Micronclean vehicles straight to their lockers on your site. In addition, we will take away used garments ready for processing in our custom built cGMP Grade B / ISO 14644 Class 5 cleanroom laundry facility.

GMP COMPLIANT PRACTICES

Our cleanroom laundry in Bangalore has been designed from the ground up to be a dedicated cGMP Grade B / ISO 14644 Class 5 facility. The processes within the laundry are based on existing UK best practice and will deliver:

- 100% visual inspection of all garment prior to processing;
- Validated double sided repairs to damaged garments;
- Validated thermal disinfection cycles giving 5 log reductions in bioburden;
- Validated thermal drying cycles to ensure that your garments comply Class A of ASTM F51-00 in terms of particulate cleanliness;
- Validated terminal sterilisation by Autoclave to ISO17665.

Within the laundry all the garments will be tracked using RFID tags in conjunction with our bespoke Protrack software. The RFID tag in each garment will ensure traceability back to batch validation data captured on our SCADA system and will maintain a complete garment history as well as delivering both routine and customised usage reports directly to you.



- 1 | Collection of soiled garments
- 2 | Full inspection
- 3 | Repairs actioned (as required)
- 4 | Washing of garments in cleanroom laundry
- 5 | Terminal sterilisation by autoclave in cleanroom
- 6 | Garments scanned back onto site with POD System
- 7 | Garments ready for use

We also have a POD system that tracks the garment from our laundry, through our dedicated delivery fleet to your premises minimising the possibility of lost garments or missed deliveries.

In this way working in partnership with you we can remove your garment worries in connection with FDA inspections.

SAVING TIME AND MONEY

Our dedicated cleanroom laundry service includes everything from measuring your staff, buying the garments, providing the lockers, cGMP cleanroom laundry practices, garment repair, delivery, routine replacement (if required) and environmentally friendly garment disposal at the end of life. This means you can focus on your core business while we focus on ours.

In addition, our inclusive garment rental model means that you don't need any capital investments to get started and with no hidden charges during the contracts lifetime you only have to pay a regular monthly charge.

THE SUSTAINABLE CHOICE

We expect your laundered garments to have a service life in excess of 50 cycles which equates to a massive reduction in the amount of waste you have to deal with.

Our cleanroom laundry has been designed from the outset to be a Zero Liquid Discharge (ZLD) facility to minimise our use of water and will utilise 150 KW of solar panels to reduce our use of electricity.

Additionally, the provision within the facility of back-up boilers and diesel generators means that we are delivering not only a sustainable solution but also an inherently robust process which ensures that you will always have your clean garments when you need them.

GARMENT RENTAL MODEL PROTRACK



PROTRACK

Micronclean use RFID transponders to track all of your cleanroom garments through our entire process. The advantage of an RFID tag over a barcode is that removes the need for direct line of sight to scan and opens the possibility of bulk scanning if this generates process benefits

Our unique in-house developed Protrack software makes full use of the advantages of RFID scanning. The fundamental difference between Protrack and most other laundry systems is that Protrack manages the individual garment and allows a high level of traceability whereas most other systems treat individual items as part of a pool. In this way we can monitor your contract and garment usage at every level from "customer" (all your garments) down to an individual garment (locker number, size, age, repairs and usage etc.)

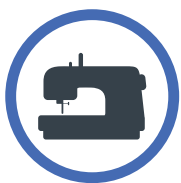
As the Cleanroom Laundry processing is highly automated, each garment's status and location is known throughout the facility e.g. checking in, inspection, repair, wash process, drying, folding, primary packing, autoclave, secondary bagging, dispatch and delivery.

Garments are assembled into a batch with the whole batch being parametrically released from the wash, dry and autoclave cycles. All batch validation data is monitored on a SCADA system along with the cleanroom environmental parameters. The RFID tag allows the specific batch validation data to be retrieved for any garment and for Micronclean to perform a batch recall if this were ever required. This data is essential for customers to demonstrate GMP compliance.

In this way the Protrack software allows us to handle individual customer or contract requirements such as:



Inspection criteria can be set to meet the customers' needs so that the individual garment details are presented at inspection.

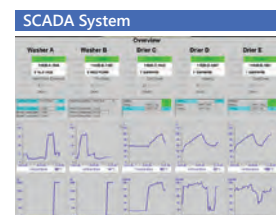


Repair criteria can be set which cover validated repair techniques and control the number and size of repairs and could invoke routine replacement of the garment.



Customised wash, dry and autoclave programmes that could include pre-set garment life criteria, wash cycles and detergent control, drying times and temperatures and autoclave process information.

Micronclean's SCADA system confirms parametric batch release for wash, dry and autoclave processes which is automatically available through Protrack.



The system allows us automatically generate reports that cover;

- Contract overview including number of garments, usage and charges.
- Garment information including issue date, last scan and number of scans.
- Repair information, by wearer, department, time period, cost centre.
- KPI dashboards that provide a KPI based overview as to the status of your contract.



GARMENT RENTAL MODEL

MICRONCLEAN GARMENT RENTAL AND SERVICE MODEL

A cleanroom garment rental service is split into two parts covering initial supply followed by a seamless transition into routine servicing which includes collection, decontamination, sterilisation and delivery. The initial supply phase covers the specification, sourcing, purchase and supply of fully prepared ready to wear cleanroom garments.



Initial Meeting

Understanding of size and scale of contract and timescales required.



Detailed Site Survey

Discuss and understand local site issues including specific site requirements including delivery restrictions, number of changes and special processing requirements.



On-Site Measurement

At an agreed time, we will come to your site and measure all your staff. This process has to be fully completed before we can order the garments.



Order Garments

After measurement we will order all your required garments. Non-standard garments will have a much longer lead time than standard garments.



Tag, Label and Process

Before a garment is issued we will apply any required badges and install the RFID tag. We will then register the garment in our 'Protrack' system so that we can monitor its entire life. The garment is then given its first decontamination to make it ready for installation.



Initial Installation

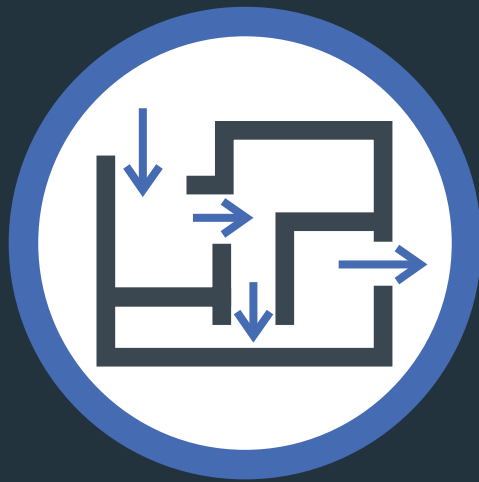
At a time to suit you we will dispatch the finished garments to your site and our personnel will install them to ensure a seamless transition.



Routine Servicing

Clean garment delivery and soiled garment removal to the agreed schedule.



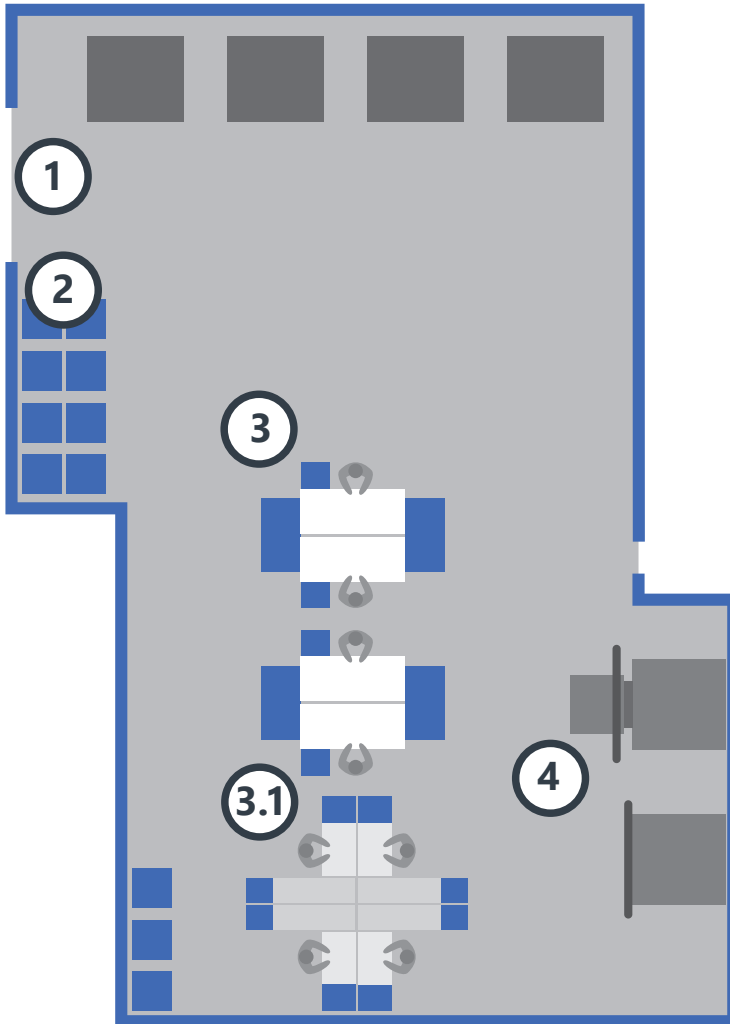


LAUNDRY FLOWCHART



LAUNDRY FLOWCHART

SOILED SIDE



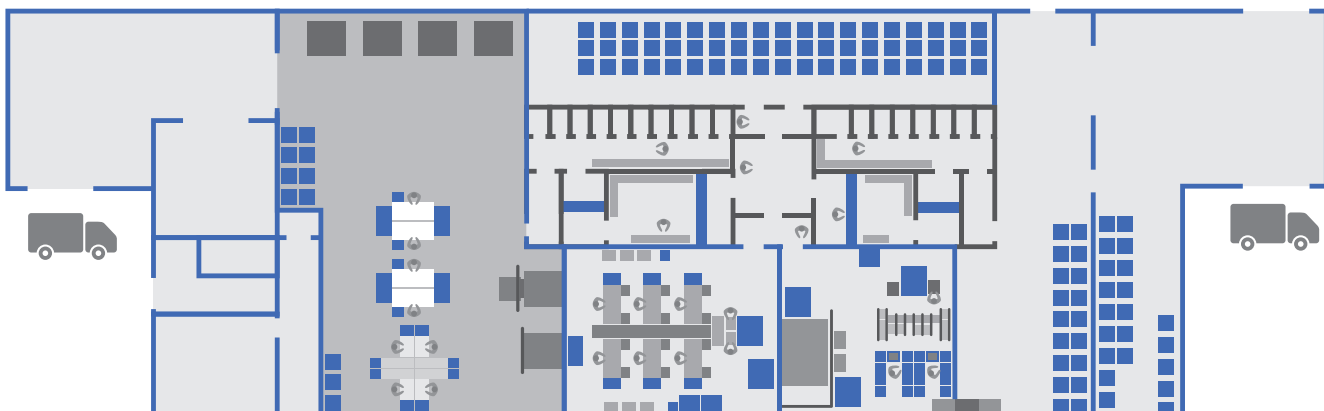
Controlled Environment

- 1 | Soiled garments are received from the customer.
- 2 | The garments are stored in Pre-Sort Trolleys.
- 3 | The garments are 100% inspected and scanned into process batches.

Optional

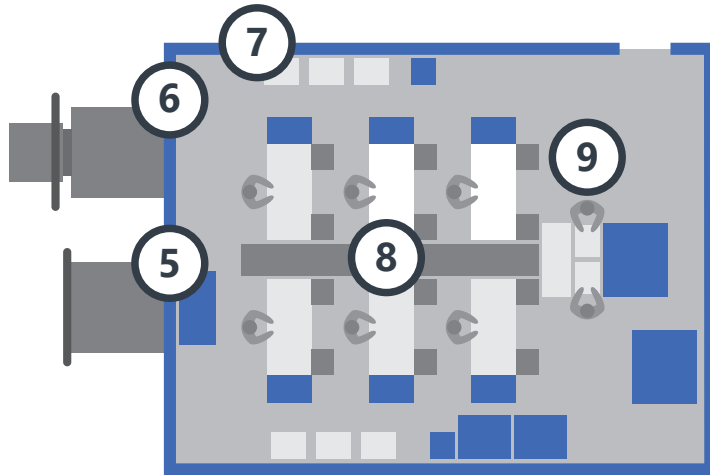
- 3.1 | Damaged garments are re-directed to sewing/repair for validated repairs. Validated double repairs are recorded in ProTrack.
- 4 | Process batches are placed into pre-wash trolleys.

All process control data is logged against the wash batch ensuring traceability.



LAUNDRY FLOWCHART

LAUNDRY



cGMP Grade B / ISO 14644 Class 5 Cleanroom

5 | The wash batches are washed in a barrier washing machine.

Garments are processed through barrier washing machines incorporating authorised and validated wash programmes.

All programmes include a validated thermal disinfection cycle (typically 71°C for three minutes) achieving a 5 Log reduction in garment bioburden.

The process is validated on SCADA using temperature time and water conductivity.

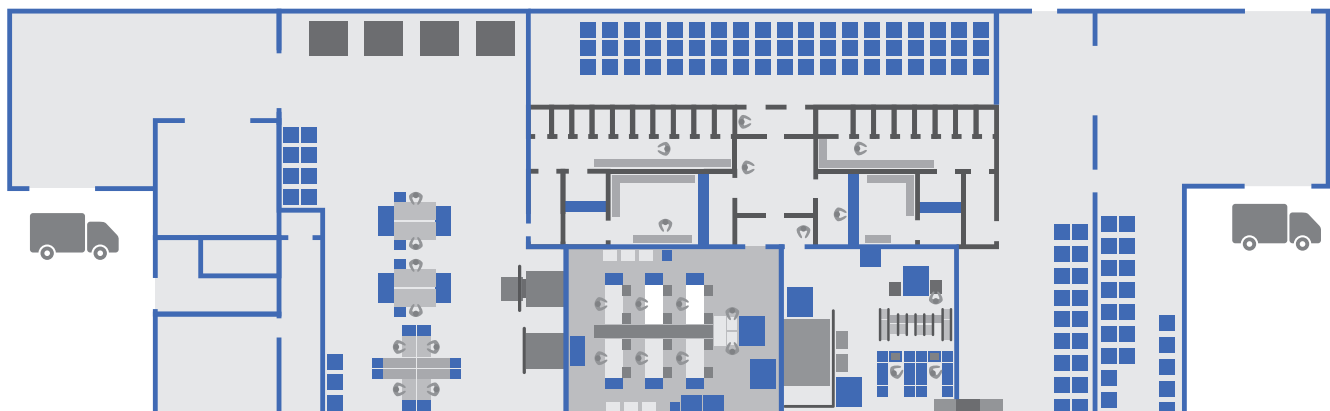
6 | The garments are Tumble Dried and decontaminated in HEPA filtered air with the tumbling chamber pressure controlled to be mid-way between ambient and the cleanroom pressure.

The process is validated on SCADA using temperature and air pressure.

7 | The dry garments are stored in the cleanroom awaiting folding.

8 | The garments are inspected, folded and placed into bags.

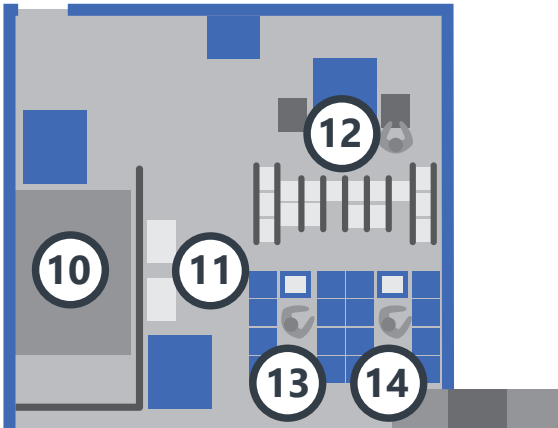
9 | Bags are hermetically sealed.





LAUNDRY FLOWCHART

AUTOCLAVE / PACKING



cGMP Grade C / ISO 14644 Class 6 Cleanroom

10 | The garments are autoclaved.
Terminal Sterilisation by Autoclave to
ISO17665.

Validated sterilisation cycle achieving at least
121°C for 15 minutes.

The autoclave cycle is monitored by SCADA.

Optional

Garments not requiring sterilisation transit the
autoclave on a pass through cycle.

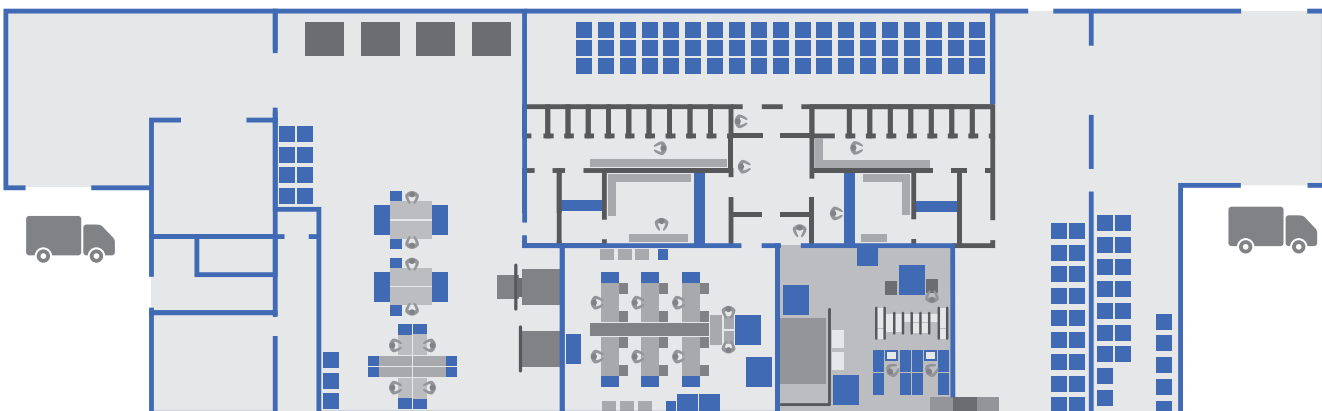
11 | Dry garments are stored prior to secondary
packing.

12 | The batch number is printed onto the primary
bag along with customisable information such
as the garment type and size.

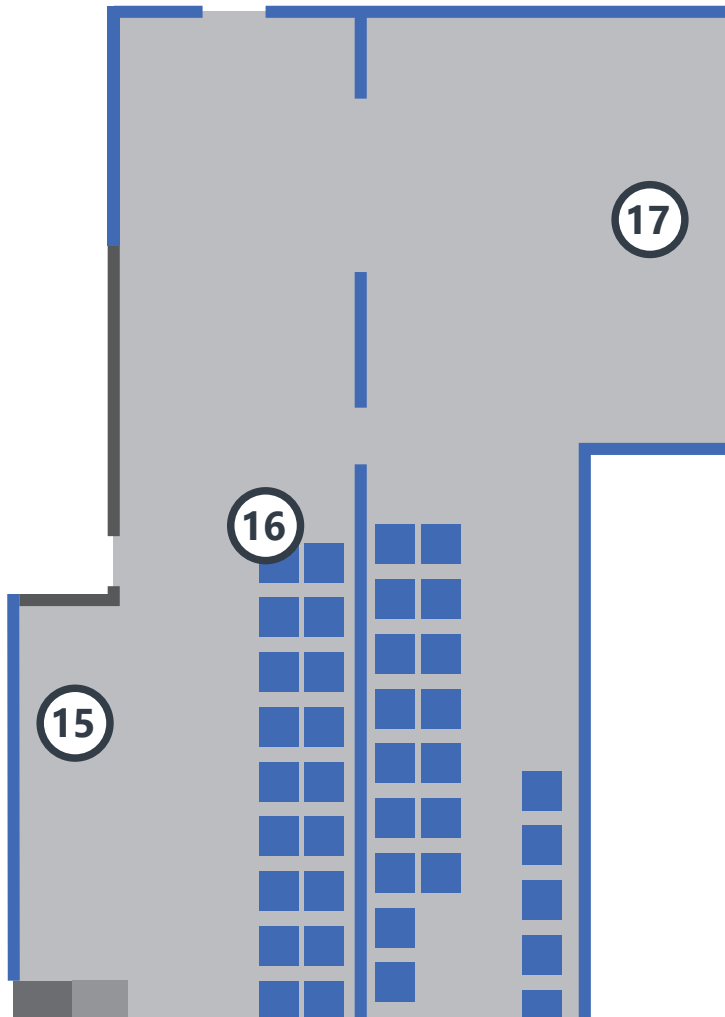
The garments are double or triple bagged
according to customer requirements.

13 | Garments are sorted on a semi-automated
system using the RFID tag. Typically garments
are sorted for a customer by product and size
if used as pool stock or by locker number if
wearer identified.

14 | Garments are placed into outer protective
bags.



LAUNDRY FLOWCHART DISTRIBUTION



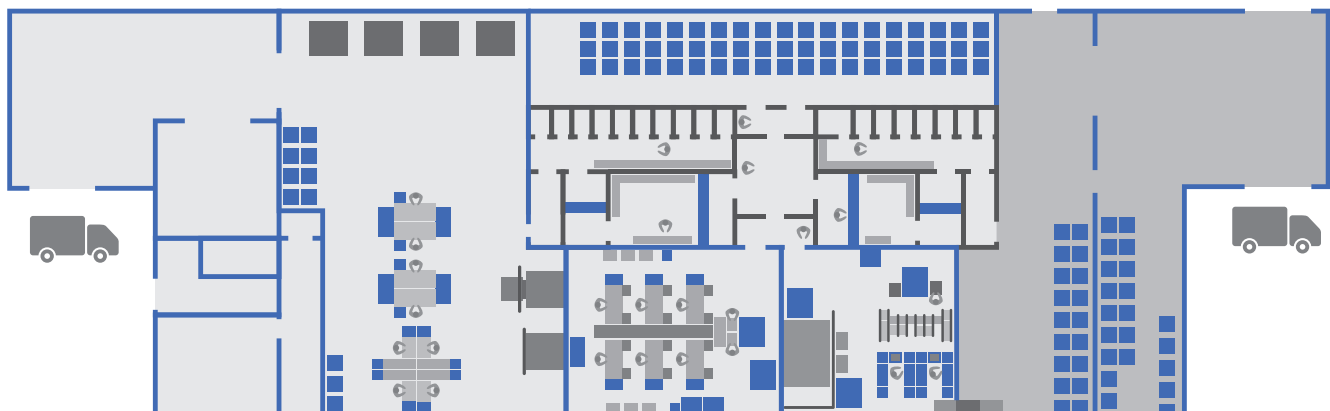
Controlled Environment

15 | The garments in outer bags are placed in hampers for transportation.

16 | The filled hampers are tracked into laundry cages.

17 | The Laundry cages are dispatched on Micronclean vehicles direct to the customer.

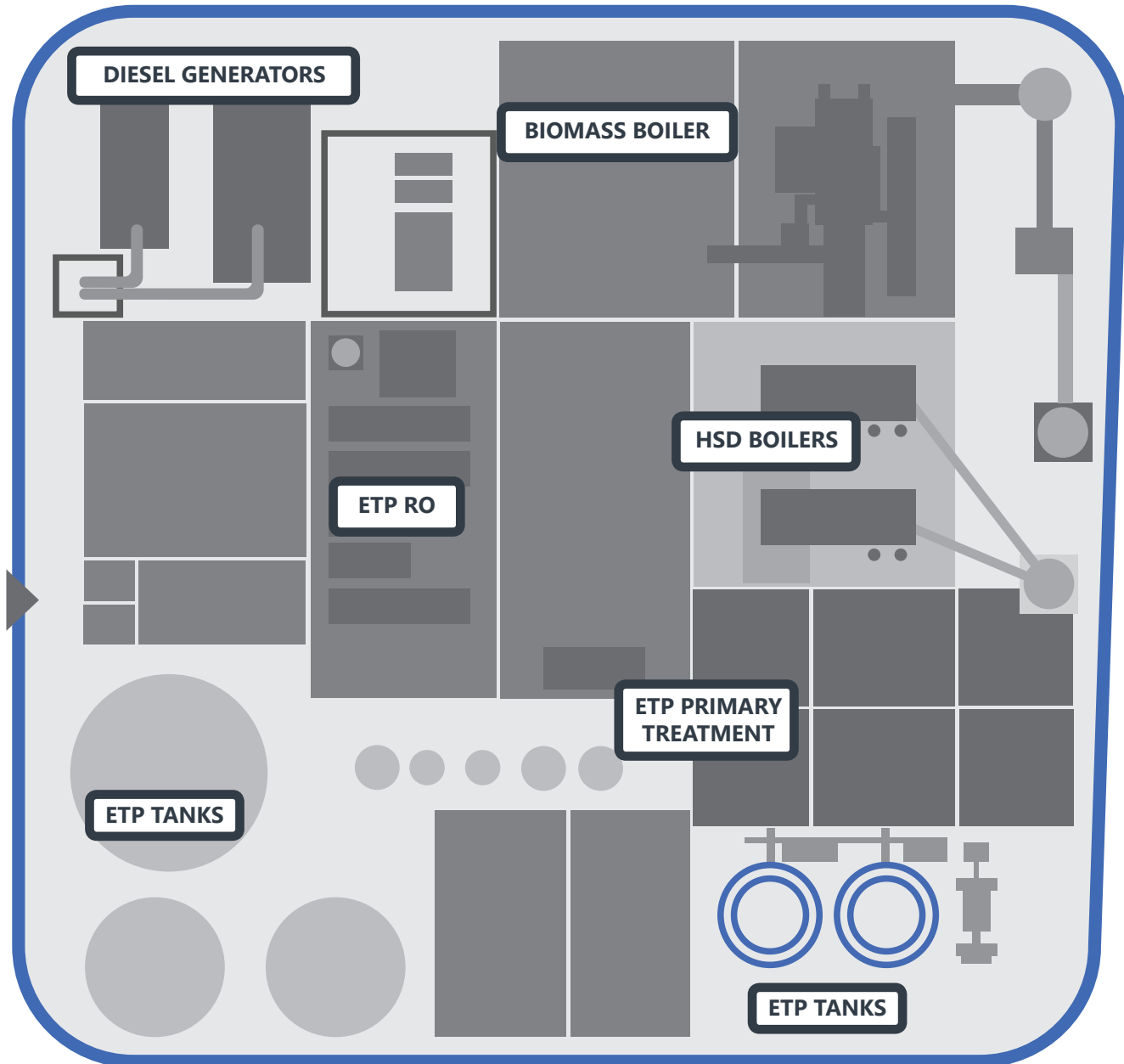
Our POD system ensures full garment traceability up to the customer premises.





LAUNDRY FLOWCHART

UTILITIES BLOCK



Utilities Block

DUPLEX HSD BOILERS to allow redundancy, particularly for annual boiler inspection.

BIOMASS BOILER to be installed once the plant volumes have sufficiently increased. Biomass is a sustainable source of carbon reducing the plants impact on global warming.

DIESEL GENERATORS to provide continuity during power outages. All IT and equipment control systems will be UPS backed.

EFFLUENT TREATMENT PLANT will utilise standard effluent treatment technology followed by carbon filtration, ultra-filtration and a 6 stage RO process. The final process water will be $<30\mu\text{S}/\text{cm}$.



CLEANROOM GARMENTS



CLEANROOM GARMENTS



CLEANROOM COVERALL **SC2**



FEATURES

Suitable for autoclaving and gamma irradiation;
Centre front zip fastening coverall;
Stud adjustments at neck, wrist and ankles;
Raglan sleeves;
Mandarin collar;
Full cleanroom construction;
Heat sealed edges;
Seams are twin needle stitched.

FABRIC

98% polyester filament yarn
2% anti-static grid


WEIGHT

105gsm

SIZES

S, M, L, XL, 2XL
Regular and Tall

STD COLOUR

 Light Blue



CLEANROOM BOOT **T01**



FEATURES

Suitable for autoclaving and gamma irradiation;
Calf length boot with elasticated top hem;
Two stud adjustment at the front and two ties attached to the heel to ensure a comfortable fit;
Dissipative flat sole;
All edges are heat sealed before sewing;
Seams are twin needle stitched.

FABRIC

98% polyester filament yarn
2% anti-static grid

STD COLOUR

 Light Blue

WEIGHT

105gsm

SIZES

S, M, L, XL, 2XL
Regular



CLEANROOM GARMENTS



CLEANROOM HOOD 400



FEATURES

Suitable for autoclaving and gamma irradiation;
Adjustable stud front fastening;
Stud adjustment at the back for improved fit;
All edges are heat sealed before sewing;
Seams are twin needle stitched.

FABRIC

98% polyester filament yarn
2% anti-static grid

STD COLOUR

 Light Blue

WEIGHT

105gsm

SIZES

S, M, L, XL, 2XL
Regular



PJ TROUSER MR9

FEATURES

Relaxed 'tracksuit' fit;
Tie waist;
Lycra ankle cuffing;
Three division accessory loop to outside right leg;
No pockets;
Fabric with ESD properties;
Long wear life.

FABRIC

100% polyester with
ESD carbon yarn

WEIGHT

195gsm

SIZES

XS, S, M, L, XL, 2XL
Regular

STD COLOUR



Navy





CLEANROOM GARMENTS



PJ TUNIC SHORT SLEEVE **MU8** | LONG SLEEVE **MU9**



FEATURES

Relaxed 'tracksuit' fit;
Front neck closure with three studs;
Two side vents;
No pocket;
No collar and edge bound neck;
Fabric with ESD properties;
Long wear life.

FABRIC

100% polyester with
ESD carbon yarn

WEIGHT

195gsm

SIZES

XS, S, M, L, XL, 2XL
Regular

STD COLOUR



Navy



VALIDATION



CLEANROOM VALIDATION

MICRONCLEAN ACCREDITATION AND CERTIFICATION

Micronclean's UK facilities and processes are professionally managed with external verification carried out by independent accreditation bodies. Our cleanroom laundry in India will work to achieve a similar level of validation.



Q5531

ISO 9001 is the most popular internationally recognised standard for certified quality management systems.



34541
Grantham/Louth

ISO 14001 is the internationally recognised standard for certified environmental management systems.



ENMS 637139

ISO 50001 is the international standard for certified energy management systems.



ISO 14065 is the international standard covering Risk Analysis and Biocontamination Control (RABC) and relation to a management system that ensures a level of microbiological quality based on the use of the garment.



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MCGEX 12/2018

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