

# Engineered Containment Solutions



Laminar Downflow Technology Designer, Manufacturer and supplier of clean air systems for the Pharmaceutical, Fine Chemical, Healthcare and Food Industry



# CLEAN AIR SOLUTIONS





# EYE FOR SAFETY

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"The future interests me more than the past, because l plan to live in it" Albert Einstein

With over 30 years of experience, CCD has become a market leader in designing high specification dust containment systems, providing industrial environmental protection, product & operator safety. A highly motivated and efficient team of experts is constantly exploring new and fresh ideas, to change and shape our future for the better.

We offer excellent customer benefits - the highest product quality, a fast delivery service and competent support. CCD is a reliable partner for its clients and a competent provider of working solutions in all areas of containment technology.

CCD is also a leading supplier of containment systems for the pharmaceutical and chemical markets. Our well-established product range includes:

**Containment Booth units** for operator protection when handling operations such as dispensing, sampling and charging.

**GMP Dispensing and Sampling Facilities** Incorporating changing rooms, airlocks, and a range of equipment such as roller conveyors, vacuum manipulators, rapid roller doors, turntables.

**Pack-Off systems** For off-loading and packing-off products with a variety of Sealing Heads.

**Reactor charge systems** Two-Chamber design with drum loading chamber, keg tipping device and transfer systems.

Solutions designed and supplied by one company.



# APPROVED QUALITY

CCD has more than 30 years of experience in manufacturing containment systems for and supplying them to the pharmaceutical, fine chemical and food industry.

# Guarantee

We guarantee complete compliance with EU standards. Our extensive internal tests are constantly being reaffirmed by external and official assessments. This guarantees the highest safety and containment standards.

The majority of our products are manufactured in-house, but the range is supplemented with high-quality third-party products, offering you a comprehensive solution for practically all your demands. Our consultants have in-depth product knowledge and the same applies to our service technicians, who have been trained at the production facilities. They are totally familiar with "their" product and are proud of it.

# Quality

Our products have to pass strict safety and quality requirements to ensure the highest quality.

Our documents include

- Quality plan.
- Qualification Master Plan.
- Design Qualification.
- FAT (Factory Acceptance Tests).
- SAT (Site Acceptance Tests).
- IQ (Installation qualification.
- OQ (Operational Qualification).
- Operations and Maintenance Manuals.
- General arrangement drawing.
- Piping and Instrumentation drawing (PID).
- Electrical drawings.

# Total containment for your applications

For our advice we take your individual local situation into account. We guarantee the best advice and support. All our advisers are professionals and engineers. Without further obligation we will provide you with an account of our findings, optionally supplemented by a risk assessment document and improvement advice. We will also supply you with a detailed overview of the required financial investments for the proposed solutions. For Concept the project does not end after delivery of the products. We will also make sure that the products can be utilised in the correct manner and we will instruct your employees accordingly. Optionally we can perform regular inspection and maintenance rounds, during which we not only check the condition of the product, but also look at the working routines and procedures.

Engineering, Design, production, Installation and Services in one hand

# QUALITY, SERVICE, INSPECTION

# Action-oriented and flexible

Regarding maintenance we are very adaptable. Small defects are immediately taken care of on the spot by our technicians. If larger repairs or part replacement is required you'll receive an estimate for the costs and work involved directly. Because both production and maintenance are in our own hands, an optimal safety level of your product, equipment or system is restored in least time possible. CCD offers you a wide range of choices in service and maintenance agreements, from a single inspection round to continuous maintenance contracts. Furthermore, our services are not limited to our own brand. Products from different manufacturers can also be maintained and inspected by CCD.

# FAT & SAT

Before you can start using any product or system, CCD has thoroughly tested it for safety. By means of a Factory Acceptance Test (FAT) at our production facility, your system is checked for compliance with all specifications. Additionally, and at your request, CCD can organise a Site Acceptance Test (SAT) after final assembly at your site. The test results will be incorporated



into an as-build SAT document. This document will attest that your safety system offers adequate protection to your employees. This duty of care is the most important starting point for occupational health and safety legislation and regulations at European level.

### Security now and for the future

Establishing a sustainable safety policy in relation to hazardous substances implies more than merely acquiring the proper products and systems. Quality service and maintenance are also essential to optimum safety in the long term. The comprehensive solution offered by CCD provides for just that with expert and professional services. Choosing CCD will therefore offer you immediate security as well as for the future.



Maintaining an adequate safety level within your organisation in the long term demands a systematic approach to the (preventive) maintenance of your safety-related systems. According to national and European legislation it is even mandatory. CCD experts have been trained to perform inspections, maintenance and reporting for you in compliance with the guidelines. In addition, CCD can offer you a custom service and maintenance contract that is optimally tailored to your specific wishes and requirements. CCD is capable of contributing substantially to the required continuity for safely handling your active pharmaceutical ingredients (APIs) by means of customisation and the right expertise.



# **OUR VISION**

Committed to providing dust containment systems to the highest standard CCD have earned a reputation for delivering outstanding quality projects which meet and exceed our clients expectations.

Delivering projects founded on openness, integrity and trust, this has resulted in long-term relationships with our clients and this is demonstrated by the amount of repeat business achieved.







### Vision & Values

Our vision:

- To be the UK leading supplier of both bespoke & standard dust containment systems.
- Supplier of choice, successfully understanding and serving the needs of our clients and customers.
- A responsibility to deliver quality and safe systems to the highest industrial standards.

We will achieve this vision by:

- Always engaging with our clients and understanding their needs.
- Consistently providing exceptional levels of service that combines efficiency, innovation and best practices.

Our values:

- Place client values at the heart of all our operations, building trust with honesty.
- Grow our business by having satisfied customers, who choose to work with us again and again.

- Take responsibility for our actions and always behave in an honest and transparent way, to the benefit of our clients.
- Always try to do what is right, being fair and open with everybody, never providing systems which are wrong or unsafe.
- Take pride in achieving excellence in all that we do. Do not tolerate under-performance in our systems or others. Never compromise on safety or quality.
- Maintain our proven track record in the successful completion of projects in which our clients are 100% satisfied, in relation to quality, specification, service and value.



Level 1

Level 2

# **PROTECTION LEVELS**

### LEVEL 1:

# CONVENTIONAL EXTRACTION TECHNOLOGY

### TECHNOLOG

Level 1 is based on conventional extraction and is used in work situations whereby the extraction point can be placed within a limited distance of the emission point. CCD supplies complete installations of extraction arms which can be used in laboratories and industrial settings.

# LEVEL 3:

# LAMINAR-DOWNFLOW

The custom-made laminar downflow booth units offer the best safety level possible based on extraction technology. Work is performed in an open space, giving the employee optimum freedom of movement and enabling them to work efficiently without obstructions.

"Best available technology." A combination of Laminar Downflow and extraction

### LEVEL 2:

# EJECTOR TECHNOLOGY, THE VARIO-FLOW GAP SYSTEM

The VARIO-Flow GAP modular system from CCD offers optimal protection due to the clean-air curtain provided by an air-injection system at the top and bottom of the work opening. The system has a fully open front, thus creating a safe and comfortable work space for your staff.

### LEVEL 4:

# ENCLOSE THE PROCESS, SEPARATE THE PERSON FROM THE EMISSION

At level 4, the emission point is separated from the user, by which the highest level of protection is achieved. This does not affect the level of freedom of movement and the worker's productivity. An example of a level 4 provision is a glove box / isolator containment.



Level 3



Level 4

# CONTAINMENT SOLUTIONS BY VENTILATION TECHNIQUES; FOR THE PHARMACEUTICAL, FINE CHEMICAL, HEALTHCARE AND FOOD INDUSTRY

Optimal safety when working with hazardous substances begins with the personal safety of your employees. The law on this point is therefore clear: Employers must complete a health and safety risk assessment identifying potential hazards/risks. When the source of the emission is to be taken away by ventilation techniques as a source shielding, effective solutions for the proper protection of operators need to be identified. Personal protective equipment (PPE) should only be used when the separation of human beings from product by ventilation is not sufficient or possible.

# **Exposure Potential and Containment Strategy**

- 1 Identify and quantify the hazardous materials and the operations.
- 2 Identify the "exposure potential" to the operator (Risk Assessment).
- 3 Identify the likely type of engineering control system/device that is required, level 1, 2, 3 or 4.
- 4 Make a selection of one of the air-protection systems on the basis of the exposure potential.

### Air-protection ventilation techniques and protection levels

PROTECTION LEVEL	VENTILATION TECHNIQUES	SHIELDING FACTOR	TASK (TRANS- FER) DURATION	QUANTITY HANDLED	EXPOSURE POTENTIAL*	HEALTH RISK (OEL) μg/m³
0	NONE	1				
1	EXTRACTION ARMS	15 - 90	short	Small (g)	low	10,000 to 1,000
2	PUSH-PULL, VARIOFLOW SYSTEMS	750	short	Medium (kg)	low	1,000 to 100
3	DOWNFLOW BOOTH	8,000-20,000	long	Medium (kg)	Medium and High	100 to 10
	DOWNFLOW BOOTH WITH BARRIER	20,000-34,000	long	Medium (kg)	Medium and High	10 to 1
4	GLOVE BOX / ISOLATORS	100,000	long	Medium (kg)	Medium and High	<0.01

\*Exposure Potential: is the factor of the quantity of loose powder transfer by manual scooping out bags, drums, etc.

# AIR-PROTECTION VENTILATION TECHNIQUES AND PROTECTION LEVELS



Uncontrolled working over a period of 2 minutes produced an average Exposure Level (OEL) of 156 µg/m³, with a peak of 5660 µg/m³.



Controlled working, over a period of 8 hours Exposure Level (OEL) < 10 µg/m³ possible.





# WHY DOWNFLOW BOOTHS

Booth units are specifically designed to offer containment of dust or liquids over large areas of emission. Booth units may be provided with a unidirectional vertical air flow to create a clean safe airflow in the worker's breathing zone. Downflow booths offer suppression and extraction of dust and vapours over the whole working area.

# CCD booth units offer operator protection for handling operations such as dispensing, sampling and charging.

- Downflow Recirculation Containment Booths.
- Downflow Single-Pass Containment Booths.
- Horizontal Laminar Airflow Booths.
- High Containment Bench Units.

# Applications

- Product Dispensary.
- Product Sampling Areas.
- Sub-Division Booths.
- Bulk Charging / Weighing.
- Product Off-Loading.
- Pilot Plants.
- Containment Facilities.
- Mixing Areas.
- Drum Charging / Off-Loading.

# Reactor charge systems

Reactor Charging.

- Two-Chamber design with drum loading chamber with keg tipping device and transfer systems.
- High-containment isolators incorporating barrier containment technology.





# CCD: THE KNOW-HOW AND CRAFTSMANSHIP OF A MANUFACTURER

# International

Concept's main office & manufacturing facility is located in the UK. Over the last twenty years we have formed close working relationships with DENIOS our partners in Europe. With this close relationship we can ensure expertise on relevant local regulations and offer the best advice & support.

### Quality

Our products have to pass strict safety and quality requirements to ensure the

### highest quality.

### **CCD Total Containment Concept**

As a specialist we have the knowledge to provide a comprehensive programme of containment solutions

- Initial quotation.
- Design and mock-up.
- Manufacturing and assembly.
- Pre-delivery testing.
- Installation.
- Commissioning and validation.
- Training.
- After-market support.
  We work with you from the initial concept right through to

after-market support.

### Features

- Customised design to suit the client's specific application.
- Designed and managed by CCD.







Laminar Downflow Booth

Laminar Downflow Booth with adjustable barrier



**Off-Loading Containment Systems** 



GMP dispensing and sampling facility

# **TWO DIFFERENT PRINCIPLES**

# Principle Recirculation booth units

A Laminar Downflow Booth is a selfcontained system designed to control potent or non-potent compounds/ powders during sampling, weighing, and other manual processes. Laminar Downflow Booth Units are used extensively in the pharmaceutical and chemical industry to safeguard operators against harmful substances generated during manual powder or liquids handling operations.



Basic principle Recirculation system for operator protection



Recirculation system for operator and product protection

In a recirculation system, 100% of the air is extracted by a high-efficiency fan/drive system, whilst providing automatic fan volume control to overcome the pressure drop as the filter dust burden increases. 90% clean air is distributed from the ceiling plenum evenly across the whole of the safety work area, pushing any respirable dust downward and away from the operator's breathing zone. As the dust moves down on a low level above the floor, high-velocity exhaust grilles direct the dust into the rear plenum. The filter system in the rear plenum with pre-pad, fine dust and HEPA filters, removes the dust before returning the clean air into the ceiling plenum. 10% of air is exhausted after the filters as a bleed to the outside area, thereby creating a slight negative environment. Typically 10% make-up Inward air movement into the Booth at low level ensures containment. The system incorporates instrumentation, air flow control, and easy access from inside for maintenance of filters, motor, fans and lights.



### **Principle Single Pass format**

A Laminar Downflow Single-Pass Booth is a self-contained system designed to control highly potent powders / liquids and solvents during sampling, weighing, and other manual processes. Laminar Downflow Single-Pass Booth Units are used extensively in the pharmaceutical and chemical industry to safeguard operators against harmful substances generated during manual powder or liquids handling operations.

In the Single-Pass once-through system, 100% of the air supply is provided by a dedicated high-efficiency fan / filter system with pre-pad, fine dust and HEPA filters, providing a downflow of clean filtered air whilst pushing any respirable dust downward and away from the operator's breathing zone. As the dust moves down on a low level above the floor, high-velocity exhaust grilles direct the dust / fume into the rear plenum. The exhaust filter system in the rear plenum is supplied with pre-pad, fine dust and HEPA filters, removing the dust before exhausting to the atmosphere. An additional 10% of air is drawn into the booth at low level from the outer area environment, keeping the booth at a constant negative pressure.

The system incorporates instrumentation, airflow control, and easy access from inside for maintenance to filters, motor, fans and lights.

10% make-up air

Supply airflow 90%

Magnehelic pressure gauges provide an instant visual indication of the supply and exhaust filter condition and supply and exhaust airflows. An electrical control panel is located at the rear of the Booth or separate from the booth to control the lights, motor, power sockets and stop/start station. Safety interlocks of the systems airflows and airflow alarm indication are included.

Optional features can include:- Fully automatic airflow adjustment. Exhaust fine dust and HEPA filters in barrier safe-change filter housings. Supply airflow with heating / cooling options. Electrical components to ATEX hazardous area specifications.



Basic principle Single Pass system for operator protection

# **PROJECT MANAGEMENT IN ONE HAND**

One contract manager for the entire process to provide short communication lines.

## Mock-up

System mock-ups for trials and ergonomic reviews are completed to ensure systems meet with our client's requirements.

### Manufacture

Manufactured utilising the latest CNC technology along with a highly skilled, in-house sheet metal fabrication facility.



### **Pre-built**

Systems are fully pre-built and tested in-house, testing is witnessed by our client before being dismantled and packed ready for shipment to site. Factory acceptance test documentation is completed.

# Installation

Installation is completed to an agreed timescale working against an approved safety and risk assessment method statement. Install gualification documentation is completed to ensure the systems conform to the requirements of the design specification.



Mock-up



Design









# TOTAL CONTAINMENT FOR YOUR APPLICATIONS. ENGINEERING, DESIGN, PRODUCTION, INSTALLATION, SERVICES IN ONE HAND

# Full validation services, FAT, SAT including IQ/OQ

- HEPA Filter test
- Laminar downward airflow test
- Airflow Quality (Particle Count) test
- Noise Level Check
- Light Level Check
- Airflow smoke test
- Temperature Control test
- Electrical test

# Commissioning

Commissioning of the system is completed after the installation qualification. Tests confirm the operational design parameters are achieved with critical instruments calibrated and recorded.

# Training

Operator and maintenance training is completed with standard operating procedures in place ensuring all systems maintain the agreed operator exposure levels.



Particle count test



Hand-over



### Service

Service contracts, annual maintenance and testing along with emergency call-outs are available.

# A COMPREHENSIVE PACKAGE OF DRAWINGS AND DOCU-MENTS WILL BE SUPPLIED

# Documentation

• All systems are supplied with a complete documentation package in line with FDA requirements. A complete documentation package is issued for review / approval within three weeks of order placement.

### **Quality plan document**

 Quality-control inspection procedures will be completed against the activities detailed within the quality plan, with information recorded and retained in the Equipment Data Book. Each activity will be dated and signed by the person responsible, with the client reviewing information and confirming each task has been completed as required. Including Project time plan (milestones) and Quality Assurance & Quality Control.

# **Qualification Master Plan document**

• The objective of this protocol is to define the Factory Acceptance Tests and Site Acceptance Tests, including Installation and Operational Qualification requirements and acceptance criteria for the Facility, for installation by the client.

### **Design Qualification document**

 The Design Qualification and associated documents are to provide verification that all aspects of the design comply with the User Requirement Specification. Include: technical specification, design calculations, fan performance curves, motor data sheets, technical specifications for main components and spare parts list.







Magnehelic gauges confirming airflow and filter conditions, all with marked safe operational sectors



### **Dedicated electrical control panels**



# FAT (Factory Acceptance Tests) document

• To confirm the system achieves its functional requirements and meets the required design requirements and quality standards.

# SAT (Site Acceptance Tests) document

• The objective of this protocol is to define the installation checks and operational test requirements and acceptance criteria for the system.

# IQ (Installation gualification) protocols and documents

 Checks to confirm the system is installed in accordance with the approved specifications and drawings. Calibration of test instruments and system instrumentation. Material test certificates; electrical test certificates; certificates of conformity for main components.

# OQ (Operational Qualification) protocols and documents

- Functional checklist; Operational tests to confirm:
- Airflow velocities, Noise levels.
- Lighting levels.
- Airflow smoke patterns.
- Filter validity testing.
- Airflow quality particle counts.

# **Certification documents**

 Include original certification documents, CEE certification and test results.

# **Operations and Maintenance Manuals documents**

 Operating procedures; Maintenance schedules; Corrective maintenance; Spare parts identification; Operator training; Maintenance training.

### Drawings

- General arrangement drawing.
- Piping and Instrumentation drawing (PBID).
- Operational Sequence Diagram.
- Electrical drawings.



# LAMINAR DOWNFLOW BOOTH UNITS FOR OPTIMUM OPERATOR PROTECTION

Suitable for many applications in the Pharmaceutical and chemical industry. Including; dispensing, sampling, milling, sieving, etc. They can offer proven containment levels of 100µg/m<sup>3</sup> - <10µg/m<sup>3</sup> (task duration).

# Design

CCD offers to provide high-quality dust and solvent containment systems, designed to maintain agreed operator exposure levels, and to provide product integrity. When you need to provide a clean, contained environment for the safe handling of powders or solvents in dispensing, weighing, sampling, or subdivision operations, CCD booths are a highly effective option.

Our senior design and commissioning engineers have over 25 years' experience working with containment systems. All systems are guaranteed to meet the agreed design criteria.

Magnehelic or digital pressure gauges provide an instant visual indication of the filter condition and laminar downflow. An electrical control panel is located at the rear of the Booth or separate from the booth to control the lights, motor, power sockets and stop/start station.

The customer need only supply three-phase, neutral and earth to the panel to enable start-up.



# DOWNFLOW CONTAINMENT BOOTH UNITS

# **Recirculation downflow booth system**

- Operating at a constant negative within the safe working area.
- No net change to outer area environments.
- Over 750 air changes per hour.
- Downward airflow at a constant 0.45 m/sec., measured 150 mm below screens.
- Fully automatic airflow adjustment to compensate for dirty filter conditions.
- Twin H13 Hepa filters 99.95% efficient.
- Airflow alarm with alarm beacon and audible sounder.
- Booth supplied complete with a chilled water cooling coil, requiring chilled water at 15 / 18 °C.
- Electrical Control Panel with Danfoss variable speed drive.
- Total airflow volume 13115 m³/hr.

# **Primary: Operator Protection**

Target operator exposure level < 10 µg/m³ over an 8-hr TWA. Realised Operator Exposure Level < 0.001 mg/m³.







# DOWNFLOW CONTAINMENT BOOTH UNITS

# Autoclave Off-Loading Facility

Four Recirculation booth modules were supplied with a total width of 18.6 m and a safe working area of 2.5 m. Construction throughout stainless steel grade 316L, 240s polished finish. Two-stage high-efficiency filtration to H14, 99.999% efficient, airflow quality to ISO Class 5 (ISO 14644-1 and Class A to GMP Annex 1 (GMP 2008)

# **Dispensing and Sampling Booth**

Sizes: 2500 x 2060 x 2300 mm (wxdxh)

- Chilled Water Cooling Coil
- Sprinkler head
- Type: Recirculation
- Total airflow: 9,700 m<sup>3</sup>/h
- Over 800 air changes per hour
- Downward airflow 0.50 m/sec.





# **Pre-Weigh Dispensary Downflow Booths**

4 No Downflow Containment Booth units Sizes: 3000 x 2000 x 2700 mm (w x d x h)

> Type: Recirculation Total airflow: 10,800 m³/h Over 650 air changes per hour Downward airflow 0.45 m/sec. Table scale, 0-3100 g (+- 0.01 g) Floor scale, 0-300 kg (+- 2g)

# **Primary: Operator Protection**

Requirement Operator Exposure Level of < 0.04 mg/m<sup>3</sup> Realised Operator Exposure Level < 0.001 mg/m<sup>3</sup>

# Powder Handling Downflow Booth

Recirculation booth with Twin H14 HEPA filters and safechange housings.







# DOWNFLOW CONTAINMENT BOOTH UNITS

# Multi-Purpose High-Containment cleaning facility booth

- Fully automatic airflow adjustment to compensate for dirty filter conditions.
- Operational modes 100% normal operation and 20% standby mode.
- Airflow quality to Class 5.
- Twin H14 Hepa filters 99.995% efficient in barrier safe-change filter housings accessed from behind flush internal covers inside the booth.
- Outer area ceiling included with bleed-air PLF screens and supply airflow diffuser.
- Booth supplied complete with a chilled water / glycol, (glycol 30%) cooling coil.
- Smoke detection pipes included in lower rear plenum.
- Removable internal stainless steel sink unit on castors.
- Left- and right-hand sloping drain tops designed to hinge back against booth rear wall.
- Left-hand sidewall with 800 mm x 750 mm aperture with raise and lower sliding door complete with limit-switch interlock and 600 mm x 1200 mm operator viewing window.
- Right hand removable bench section with 250 mm diameter bag disposal port.

# **Primary: Operator Protection**

Requirement Operator Exposure Level of < 0.02 mg/m<sup>3</sup> Realised Operator Exposure Level < 0.001 mg/m<sup>3</sup>







# SINGLE-PASS SYSTEM

# **Containment Booths System**

- Full internal stainless steel construction.
- With input and exhaust alarm beacons.
- low-level flush-mounted vacuum connection point complete with hinged flap cover. Also a vacuum start-stop station complete with green run indicator lamp.
- Booth rear wall fitted with a stainless steel support 200 mm x 60 mm to carry up to a maximum weight of 100 kg.
- Fine dust and HEPA filters mounted in barrier safechange filter housings accessed behind flush-mounted rear wall covers inside the booth.

Sizes: 2300 x 2200 x 2900 mm (w x d x h) Total airflow : 6,155 m³/h ATEX, Zone 2



WARD AIRFLOW ALARM



# DOWNFLOW CONTAINMENT BOOTH UNITS

# Processing LAF Booth

- Recirculation airflow format booth system operating at a constant negative pressure. Designed to meet current FDA requirements.
- Construction from full stainless steel grade 304, 240s polished finish. Double skin construction with a minimum number of joints, mounted onto a coved section plinth.
- Downward airflow velocity at 0.475 m/sec. at 150 mm below PLF screens.
- Airflow quality at 150 mm below PLF screens to ISO 5.
- Booth bleed-off to atmosphere fitted with TROX VAV for 10% & 100% airflow volumes.
- Supplied with a chilled water cooling coil.
- Booth operating with over 700 air changes per hour. Bleed airflow to atmosphere.



Printer housings

- 10% standby mode and 100% operational modes.
- Remote electrical control panels with Danfoss VSD, pressure transducer, safety relay, Photohelic airflow alarm and booth lighting supply.
- 2 x Printer housings. Printers mounted on slide-rails accessed from outside the booth with internal removable front cover with printer label slot.
- Waste bag outlet 300 mm diameter mounted below printers.
- ATEX fan unit with copper end-plates and anti-spark features, ABB ATEX zone 1, 21 motors, complete with temperature thermistors. Direct-drive Omega coupling between the fan and motor.
- G4 / F9 & H13 Hepa filter conditions are monitored by pressure transducers providing a O-10 V signal to allow client remote monitoring of each booth's filter conditions.
- Additional bank of activated carbon filters to remove odours from within the recirculation airflow system.

# **Primary: Operator Protection**

Target operator exposure level <25 - 50  $\mu\text{g}/\text{m}^3$  over an 8-hr TWA. Realised Operator Exposure Level < 0.001 mg/m³



Smoke test





Recirculation downflow booth unit Designed as ATEX zone I environment

- Operating at a constant negative pressure.
- No net change to outer area environment.
- Over 700 air changes per hour.
- Bleed air ducted to atmosphere via HVAC.
- Electrical EMC panel in technical area above the system.



Off-Loading Suite Containment Systems



### System designed to suit FDA & cGMP requirements

- Viewing windows in both side walls.
- Booth supplied complete with chilled water cooling.
- Twin H13 Hepa filters 99.99% efficient in standard filter housings accessed from behind flush internal covers inside the booth.
- Removable bench units.
- Magnehelic gauges with marked safe operational sectors confirming airflow and filter conditions.
- Vacuum start button on booth rear wall, for client vacuum system.
- For powder dispensing target OEL <25 ug/m<sup>3</sup>.
- Realised Operator Exposure Level < 0.001 mg/m<sup>3</sup>.





Laminar downflow Airflow Ceiling Plenum Designed for installation below clean room ceiling Construction full stainless steel grade 316L

# **GMP FACILITIES**

# Top plenum fully welded construction, including

- H14 HEPA (99.999% efficient ) gel-seal filters located onto knife-edge profiles.
- High-frequency fluorescent light units T5 to provide a minimum of 700 lux at 750 mm above floor level.
- PLF airflow distribution screen frames.
- Measuring points to confirm 100% challenge on filters during integrity testing.
- Antistatic curtains with stainless steel reinforcement on base.

# Grade A zone to GMP Annex 1

Airflow test methods to EN ISO 14644 3

Classification of air cleanliness to ISO 146441



# Laminar downflow unit (LAF)

Manufactured throughout from stainless steel grade 316L, 240s polished finish. mounted in the clean room ceiling.

Rear wall and top front plenum included 6 No. Rotor motor fans with speed controllers providing balancing of the system airflow. Controlled by the BMS system client.

Guaranteed to withstand disinfection with hydrogen peroxide (H O ).

PLF screens, filters and lights easily removable for maintenance / replacement.

Designed to operate at 0.45 m/sec. at working height 1.0 m above the floor level providing a "Grade A" zone environment.

Guaranteed designed to operate at 0.45 m/sec. or +/- 10% 150 mm below PLF screens. Test method to ISO 14644-3.

Airflow quality Class A to GMP Annex 1 (GMP 2008) (<0,5 and 5,0 µm/m³). Test method to ISO 14644-1 at working height 1.0 m above the floor level.

Downward airflow volume 22,680 m³/hr. Fresh air from building HVAC at 3,000 m³/hr.



### Laminar downflow booth

Primary: Operator and Product Protection Requirement Operator Exposure Level of < 0.04 mg/m<sup>3</sup> Realised Operator Exposure Level < 0.001 mg/m<sup>3</sup>

Airflow quality Class A to GMP Annex 1 (GMP 2008) (< 0.5 and 5.0  $\mu\text{m/m}^3\text{)}$ 



# **Sampling Facility Unit**

Sampling Facility complete with Materials Entry / Exit, Lifting Hoist, Personal Air lock, Materials Air locks with automatic conveyors and Sampling Containment Booth System. Include automatic IPA disinfection section.

- Design complies with the User Requirement Specifications for Sampling for small and large packages.
- Internal full stainless steel. Outer sidewall double skin construction, zintec steel, epoxy polyester powder coated panels.
- Clear anti-static strip-curtain entry in two sections mounted on slide-rails.
- Above the facility a Dx Condenser rated for 22.0kw of cooling provides air to the facility at 21 degrees.
- Operating Modes Siemens PLC Controlled.

# Material Entry / Exit

- 10 air changes per hour.
- Air quality ISO 8.
- Pallet protection rails.
- Stainless steel roller tracks.
- Automatic glass sliding doors.
- Intercom communications system.
- Local operator controls station for raise / lower doors.
- vacuum lifting system for the loading and off-loading of bags and containers.



Material Air Locks with Dray spray system for IPA disinfection



Sampling Booth





# Personnel airlock

- Minimum 10 air changes per hour at 25 Pa.
- Air quality ISO 7.
- Air lock doors with kick-plates and magnetic interlocks.
- interlock with emergency overrides
- Stainless steel Step-over bench.

# **Material Air Locks**

- 10 air changes per hour at -15 Pa.
- Air quality ISO 7.
- 2 chambers for decontamination and drying.
- Front sections with stainless steel in-fill panels and hinged doors with laminated glass vision windows.
- Chambers fitted with raise / lower pneumatically operated clear vision doors. Door clear opening aperture 1300 mm wide x 750 mm high, doors interlocked to prevent simultaneous opening.
- Automatic flat belt conveyor system.
- Dray spray system for IPA disinfection.

# Sampling Booth

- 700 air changes per hour.
- Airflow quality ISO 5.
- Emergency access in booth to the "kick-out" panel.
- Adjustable height raise / lower table, height between 550 mm to 850 mm.
- Intercom communications system.



- Magnehelic gauges confirming room operational pressures, traffic light room operational mode indication, booth airflow, AHU airflow, Oxygen and IPA alarm beacons / sounders.
- Dedicated Solvents extraction system in back wall booth.

### **Primary: Operator Protection**

Target operator exposure level < 10  $\mu$ g/m<sup>3</sup> over an 8 hr TWA. Realised Operator Exposure Level < 0.001 mg/m<sup>3</sup>.





# SAMPLING FACILITY UNIT

### Personnel Entrance room

House in House system. Epoxy floor with coved finish. Extended wall panels to building, manufactured from self-supporting clean room walls, mounted on a recessed plinth, 80 mm thick sandwich panels, sheet steel epoxy coated with PUR foam core. Ceiling manufactured from 100 mm thick panels complete with supply air diffuser and flush mounted ceiling lights and emergency lights. Lighting controlled by movement sensor. Joints are sealed with Dow Corning 798 clean room silicone. Changing room operating at +5 Pa.









Magnehelic gauges with marked safe operational sectors



Main control panel With Siemens S7-300 PLC and 10" HMI screen





# Sampling Booth

Fully automatic airflow adjustment with 50% standby and 100% operational modes to operate at -10 Pa with Small reach dedicated extraction arm over the table for sampling small containers with solvents.

## **HMI Control panel**

Installed flush into the wall of the Sampling Booth in order to inform operators of the process and operation status, as well as pallet availability. Pallet receiving and sendoff can be operated from this panel. It is also possible to operate the pallet turntable.





**Keyboard** On sliding shelf below main bench unit.



Louvre grilles Stainless Steel 316L, 240s polished.



Pallet turntable Heavy Duty Stainless Steel 316L in floor Sampling booth. Controlled from the HMI screen inside the booth and interfaced with the main conveyor system.



Traffic Alarm Beacon



Pallet entry / exit door High-speed, self-repairing automatic sliding door, fitted with open / close limit switches.

# A complete comprehensive list of options, accessories are available to customise the Booth to your requirements and to suit any containment application.

- Available in epoxy coated zintec steel, stainless steel AISI 304 / 316L or a combination of both
- Double-skin side panels
- Coved section plinths or base plinths to enable coving by client
- Freestanding or fixed bench units in various widths and heights
- Weighing tables
- Safe-change filter housing
- Cut-outs for the integration of a computerised management system, printers and monitors
- Visual and audible alarm packages
- Penetration for piping and sprinklers
- Cooling and heating systems
- Dedicated exhaust systems
- Doors with interlock systems
- Windows in side walls or doors
- Pallet protection rails
- Rapid roller doors

- Turntables
- Vacuum lifters
- Drum tippers and manipulators
- Post hoists
- Roller conveyors and turntables
- Lifting and tipping systems for drum handling equipment
- Range of filter systems pre-pad, fine dust, HEPA and Carbon
- Waste bag outlet with continuous liner outlet
- Explosion proof systems (dust and gas environments) for Zone 1 or Zone 2
- Personnel and materials airlocks
- House in House systems
- Variable speed drives with fully automatic airflow adjustment for fans for progressive filter blockage
- 20% Standby & 100% Operational modes
- Containment screen (barrier) with glove ports for improved operator protection (OEL < 10 µg/m<sup>3</sup>)
- Utility services such as breathwing air, water, Nitrogen etc.









# **OPTIONS AND ACCESSORIES IN ACCORDANCE** WITH USER REQUIREMENTS



**Utility services** 



Sprinkler head



Vacuum systems



Pallet protection rails



Integration of a computerised management system, printers and monitors



**HVAC** systems



Safe-change filter housing



Visual and audible alarm packages



Vacuum extraction system with 3-phase safe-change filter housing



# CONTAINMENT DESIGN IN ACCORDANCE WITH USER REQUIREMENTS

Stainless steel tables with adjustable height levelling feet, Trespa top and extraction plenums. On both sides of the plenum removable exhaust grilles and stainless steel washable mesh filters. Tables to operate between 425 mm & 725 mm, (300 mm adjustable height), controlled by raise / lower push buttons. Exhaust ducted to dedicated fan / filter plenums with HEPA filters.



Recirculation bench unit with hopper and dedicated extraction, connected to a reactor







Exhaust grilles across upper bench face and high containment exhaust.



Laminar downflow containment Bench Units, Single-Pass downflow, operating a constant negative pressure.

- Full stainless steel grade 316, 240s polished construction.
- Laminar Downflow at 0.35 m/sec. when measured 50 mm below PLF distribution screen frames.
- Supply and exhaust airflows complete with safety operational interlocks.
- Supply airflow plenum fitted with G4 pre-filter and F9 fine dust filters 98% efficient.
- System lighting levels >600 Lux at 1.5 m above floor level, fitted with high-frequency T5 fluorescent lights.
- Bench top and adjustable height section.
- Equipment pass-through aperture with nylon sliding door.
- Removable perforated equipment shelves
- Supply airflow drawn from room environment, downflow at 0.35 m/sec. at 50 mm below PLF screens.





# Atex zone 1







# **REACTOR CHARGE AND OFF LOADING SYSTEMS**



### Product off-loading system

Systems designed to suit the client's required operator exposure levels and offer primary dust containment when off-loading and packing dry powdered product in the pharmaceutical or chemical industry.

- Product discharge chute complete with outward inflating membrane seal.
- Continuous liner cartridge.
- Nitrogen purge facility.
- Integrated weighing system.
- Low- and high-level filling system extraction.
- Head extract completed with pre-pad dust filter.
- Dedicated pneumatic control panel.

# Glove box units

- Negative pressure glove box isolators to allow contained dispensing of product from bags.
- Once-through airflow design under a constant negative pressure with 736 m<sup>3</sup>/hr exhaust to atmosphere.
- Full stainless steel construction with radius corners, crackand crevice-free.
- G4 filtered inlet and F9 filtered outlet.
- Front hinged product loading door c/w vision panel with oval glove-ports and gauntlets, door fitted with gas-struts.
- Continuous liner and 225 mm diameter waste disposal port.
- Door in- velocity >0.35 m/sec. Glove failure in- >1.0 m/sec.
- Safe area electrical control panel housing extraction controls via shut-off dampers.
- Fluorescent light unit. Glove box internal lighting level
  >400 Lux.







# EXTRACTION FACILITIES AND INSTALLATION

Whether it is a local extractor, a VARIO-Flow GAP workstation or a laminar downflow system, all air technology facilities must be connected to an extraction system. This can be a simple fan or a recirculation system, but can also be a more complex air management system for several facilities or rooms.

Our specialists calculate the required capacities and our engineers design your extraction installation. Installation on location by highly qualified CCD mechanics.

Back-up system



ALSO AVAILABLE: AIR TECHNOLOGY SAFETY LEVEL 2



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# PRACTICE CASES

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# SAFE SEED COATING ON A LABORATORY SCALE

At seed improvement company Syngenta in Enkhuizen, costly seeds are coated with plant protection products by hand on stainless steel work tables. New laminar flow booths with bottom exhaust systems keep the exposure risks for workers well below the legally required minimum levels.

Author: Vincent Hentzepeter | Photography: Foodnote

At dusk, the greenhouse complexes alongside the offices, production areas and laboratories of Syngenta in Enkhuizen are lit up beautifully. Horticultural crops and flowers are cultivated here for improvement research. The advanced small seeds that emerge can cost several euros a piece. The flowers and horticulture sector can thus increase its yields, reduce the use of chemicals, improve quality and maximum profits.

The coating of these valuable seeds with crop protectors is a delicate process and is therefore done manually on a laboratory scale. Up until last year, the Coating division still worked with localised extraction to protect workers from exposure to substances. Syngenta thus met the occupational health and safety requirements, but the company wanted to go a step further to remain well below the exposure limits now and in the future. This led to the decision to integrate three workplaces and two washing rooms in laminar flow booths. The downward air flow from the ceiling to the rear of the work tables and booths keeps hazardous substances out of the breathing zone. Validation of the units points to a significant improvement in the air situation and thus an improvement in the occupational health and safety conditions of the workplaces.

# **Precision work**

In the Coating division, workers spray various types of liquid over the seeds in a sort of pan. The agents protect seeds, which come from worldwide cultivation programmes, for example against fungus. This coating on a laboratory scale is real precision work. After each series, the worker determines the final weights to see whether the correct amount of crop protector has been used and checks the seeds for adhesions. No seed may be lost, and there are fine sieves in the sink



Panorama of the downflow booths.

to catch everything. After each batch everything is checked, there must be no foreign seeds at all in a coated batch. The lab then checks for features not visible to the eye that the coating must possess. The batches vary from grams to kilos.

concept

### Syngenta standards

"We want minimum contact with the agents for our workers," says Jeroen Greiner. He is project manager in the facilities division and coordinated the project with the laminar flow booths. "We spray the slurry straight onto the seeds. These products are not good for people's health. With the old localised extraction, the exposure was too high by Syngenta standards. We met all the legal safety requirements, but Syngenta sets the bar high within the crop protection sector. The requirements in that regard are implemented throughout the company, in other words also rolled out to the seed division. We wanted to gain more control over the situation here logistically and in terms of substance management. These are toxic agents, lighter than coffee whitener. Such localised extraction works well on the coating machine, but less so in the surrounding area, where you have to tip the seeds out."

# Safe barrier

There followed a search for a suitable solution. "In the preliminary stage, we focused on the offer together with an engineering firm. I had already seen the principle of the new set-ups we chose on the DENIOS stand at a trade fair. At the time it already appealed to

me. That became the starting point for the design of an installation with which we create a safe barrier between the worker and the process. This is guaranteed by the air management of the booth. We had three built for coating and two in which washing rooms with eye showers were integrated," says Greiner. Units with tables were chosen, whereby the booth cannot be entered. Greiner: "We felt it was easier to place the apparatus on tables in the cabinet, from where the air is extracted straight to the outside via a central exhaust system. A return system was less appealing to us, because if there's a disaster with the filtration installation you run the risk of dust being carried into the cabin via the return line. The extracted air passes through a high-efficiency heat exchanger. So we've physically separated the air system, but we can recover as much energy as possible for hall heating."

### Trial model

Right from the start Greiner involved his colleagues in the plans. He first had the set-up with the tables in a booth tested in practice. "CCD installed a trial model of MDF board in a steel frame on site. This allowed workers to experience whether the theory actually works in practice. One time right,



"We want minimum contact with the agents for our workers," says Jeroen Greiner, project manager in the facilities division.

that's what we were aiming for." The experiences revealed specific needs that were implemented in the final design. "The platform was adapted and the steel bucket for the seeds is now height-adjustable. There was also a request for a water barrier round the edge and a grille under the tables. To organise the booths properly, they wanted a plank in each unit to put things on. We work according to the 5s principle, everything has a fixed and logical place." All in all, quite a few areas for improvement. "Here you can see the added value of the trial model. By involving workers in the design process from an early stage, you create a well-thought-out and feasible design.

# FAT and SAT

Six weeks later the Factory Acceptance Test (FAT) took place at the manufacturer in England. A test to check the cabinet from the perspective of ventilation. During the FAT we also closely examined the finish of the sockets and intake points. The finishing touch was the raised edge of around one centimetre. The surface of the table must be perfectly smooth to be able to make the sheet clean, but if you spill liquids, the raised edge means you can keep everything manageable within the table." At the Site Acceptance Test (SAT) in Enkhuizen everything seemed to work perfectly. "We carried out the SAT in consultation with the filter installation supplier. It has to ensure sufficient suction capacity. We checked all the safety features. Only when the light comes on and the afzuiging is working there is also power to work. If the afzuiging is not working, the coating machine must be switched off and remain off until this has been rectified. All alarms were also checked. In the booth, the operator can see visually whether it is safe to work. This is only possible if the light is on."

# Leading the way

In January a stationary test was performed with concentration measurement on the open side of the cabinet, where the operator works. This shows that the situation has improved significantly. "If we put the measurement data from the periodic health and safety at work study next to each other and compare the old and new situation, then we can say that Syngenta are leading the way in terms of health, safety and the environment. We want to be well below the standards. When you know that the requirements are becoming ever stricter, you have to include technical provisions for this in your design. These cabinets will be in use for ten to fifteen years, and all that time they will have to constantly meet the legal standard. A safe and healthy working environment is extremely important to Syngenta."

# Training

The installations were installed plug and play, so that the process could continue. "During the SAT, workers in the project team were instructed in the process and the cabinet. With this information, main users can guide their colleagues through the new process. This meant we could commission the system quickly. There was also basic training for users and the technical service, to allow them to remedy any initial faults." LM



Switch unit. On the table are bags of high-tech seeds.



# OSS - LAMINAR DOWNFLOW BOOTH UNIT AT MSD:

# Maximum safety is therefore guaranteed for the operators.

Two MSD employees and a project engineer from project partner DHV talk about the custom-made Booth Unit CCD/DENIOS delivered to MSD Oss.

# **'Custom-** Mark Spelmink, Production Engineer, Technology (MSD)

"As internal project manager, I was involved in the technical set-up and arrangement of the laminar downflow booth unit. This contains the weighing area, where products, which are sitting dry on a plate, are emptied into barrels. This releases a lot of dust. The 'downflow' ensures that this dust cannot reach the operator, who can therefore work safely. Merck set the bar higher - we already satisfied the Dutch standard - and wanted to reduce the amount of active substances to zero. We achieve this among other things with the CCD/DENIOS booth unit custom-made for MSD!"



# Advice

made

from

**Booth Unit** 

**DENIOS'** 

"During the tender process, everything was discussed down to the last detail and a suitable bid was made incorporating all the requirements and wishes of MSD. Advice was also given on the maximum height in relation to the air flow to prevent unnecessary vortices between the CG Cloth and the ceiling of the unit!" says Mark. He continues: "The difficulty lay in the fact that the entire installation had to be installed in low rooms that are also hard to access. CCD/DENIOS knew what to do, and constructed the whole thing carefully to create a completely workable situation!"



# Permanent coordinator

Finally, Mark points out: "We're extremely satisfied with CCD/DENIOS and its products. But above all with the fact that we were assigned a permanent coordinator from DENIOS who was at our side with advice and expertise for the entire project. We've not yet had and experience with aftersales, because everything is working well. We were even supplied with extra filters without being charged by DENIOS!"



### Extreme safety with Laminar Downflow

Containment systems, such as laminar downflow booth units and laminar downflow bench units, protect operators from hazardous substances that may escape during manual product operations. Various ventilation technologies are available with a very high level of protection, with the operator retaining complete freedom of movement.

Laminar downflow booth units are mainly used in the pharmaceutical, chemical, cosmetic and food industries. They offer extremely good protection from exposure to hazardous substances. The user has complete freedom of movement. The work can be carried out under the best conditions. This leads to a significant increase in productivity. The booths are available with recirculation or single-pass technology; in a design that complies with Good Manufacturing Practices (GMP) and meets the requirements of the Food and Drug Administration (FDA); with personal protection, with product protection and with personal and product protection.

Agreements are made with the client beforehand on the objectives to be achieved. In recent years CCD/DENIOS has implemented various projects for producers in the pharmaceutical and fine chemicals industry.



# Fred Bongers, Quality Assurance Officer (MSD)

Fred Bongers was section leader of the sampling group at MSD in Oss. This group is the user of the booth unit in relation to the sampling of non-active raw materials (excipients). "The reason for MSD to install the booth unit was to meet the new requirements in terms of GMP regulations. CCD/DENIOS understood what requirements the booth unit had to meet and had a mock-up constructed at CCD in England on the basis of the URS (trial model 1:1). They even took account of possible stricter regulations. The new installation consists of a laminar downflow booth unit supplied with class A air and a personnel/goods airlock with class C air. DENIOS delivered the entire installation, including the necessary overpressure and underpressure spaces, cooling and heating systems, air treatment cabinets, filters, interlocks and control systems.



### FAT and SAT

"During the development period of the booth unit we travelled to England on two occasions. The first time, the booth unit, as I've already said, was put together as a true-size trial model in wood. We had ample opportunity to make changes to the design, which ultimately were all approved. The second time, the booth unit was already in the form that would be delivered to MSD, in accordance with requirements and wishes. The FAT (Factory Acceptance Test) was passed well. During installation in situ, everything within our power was done to stick to the plans. When the SAT (Site Acceptance Test) was also successful, delivery was made!" says Fred Bongers.

# Staff are entitled to a safe workplace'

# Short lines

Fred continues: "From the outset, MSD was assigned a permanent coordinator from CCD/DENIOS. We liked this a lot, because it means the communication lines are short and there's no unnecessary noise."





### Gerard van de Camp, mechanical engineering project engineer (DHV)

"Since 2007 I've been working constantly on a project basis at MSD from DHV Eindhoven. This means I'm very familiar with the internal guidelines and standard documents. In the preliminary stage, the relevant division within MSD, in collaboration with a third party, produced a URS for a booth unit. A design was then produced, and based on this an invitation to tender was issued to a number of parties, with DENIOS coming positively to the fore with a total solution. Within MSD, CCD/DENIOS is a familiar supplier of booth units and was able to satisfy all the conditions at a competitive price. From that moment the remainder of the project was implemented by DENIOS under the leadership of DHV."

# 'Mock-up'

"The main reasons for buying such a booth unit were product protection and personal protection. A 'mock-up', a life-size wooden model, was produced so that the customer could see and experience what would be delivered. This resulted in a number of optimisations in terms of installation heights and design of a number of components. The complete installation was put together at the manufacturer, so that it could be fully tested and checked during the FAT. This was done to avoid disrupting the process at MSD and reduce the lead time. The installation was then dismantled and assembled in Oss, after which the SAT and then qualification were successfully performed. For product protection and personal protection, the booth had to deliver a downflow of 0.45 m/s and an air quality of class C. However, the air quality in the booth even complies with class A!"

# 'DHV as designer and DENIOS/CCD as supplier'

# **Collaboration with DENIOS**

"The lead time from the 'mock-up' to delivery was around 4 months. It was a complex project because there was little space available for the installation. DENIOS implemented the project professionally and flexibly together with CCD from England!" concludes Gerard.





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