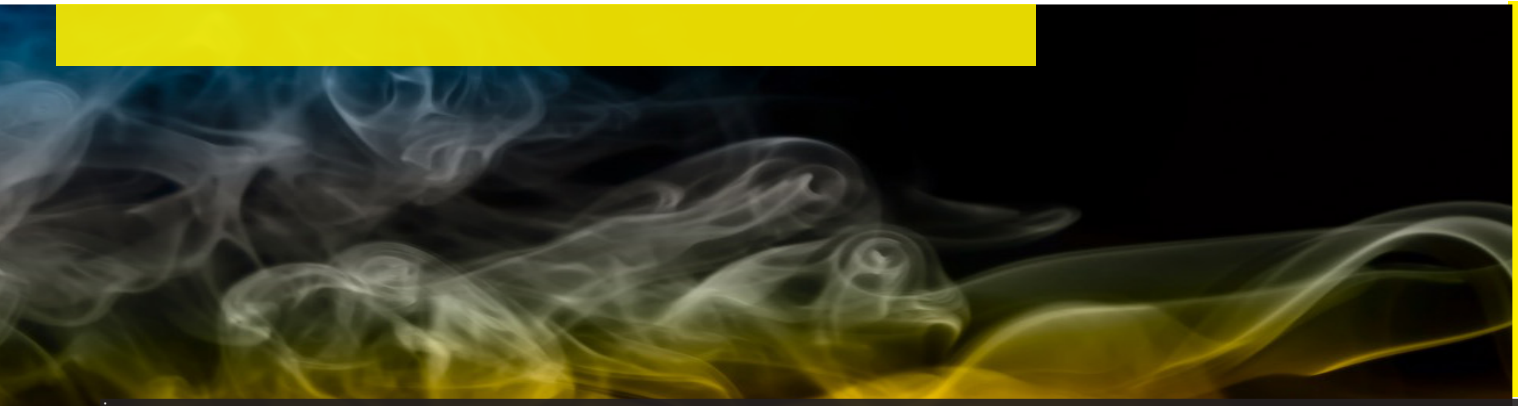

SERVICES

Airflow Visualisation

WE PROVIDE AIRFLOW MAPPING, CERTIFIED TESTING SERVICES, SALES AND HIRING OF AIRFLOW VISUALISATION EQUIPMENT

opira.com.au

CLEANROOMS ARE DYNAMIC SYSTEMS. PEOPLE AND GOODS ARE CONSTANTLY IN MOTION. INSTALLATIONS, PRODUCTION LINES AND MACHINES DO REQUIRE PERIODICAL ADJUSTMENTS TO THE PRODUCTION OF DIFFERENT PRODUCTS. ACC. TO THE RELEVANT STANDARD ISO 14644-3, THE OPERATORS OF CLEANROOMS ARE OBLIGED TO GIVE PERIODIC EVIDENCE OF THE IN-SITUE AIR FLOW SITUATION BY AN AIR FLOW MAPPING SUPPORTED BY HIGH-PURITY AIR FLOW MAPPERS.

SERVICES

Opira offers Airflow Visualisation testing to our clients who operate processes under the requirements of the new PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PICS) GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (GMP).

The guidelines specify PIC/S GMP Guide (PE 009) requirements: 2022. Annex 1 Section 4.15

4.15 Airflow patterns within cleanrooms and zones should be visualised to demonstrate that there is no ingress from lower-grade to higher-grade areas and that air does not travel from less clean areas (such as the floor) or over operators or equipment that may transfer contamination to the higher-grade areas where unidirectional airflow is required, visualisation studies should be performed to determine compliance (see paragraphs 4.4 & 4.19). When filled, closed products are transferred to an adjacent cleanroom of a lower grade via a small egress point; airflow visualisation studies should demonstrate that air does not ingress from the lower grade cleanrooms to the grade B area. Where air movement is shown to be a contamination risk to the clean area or critical zone, corrective actions, such as design improvement, should be implemented. Airflow pattern studies should be performed at rest and in operation (e.g. simulating operator interventions). Video recordings of the airflow patterns should be retained. The outcome of the air visualisation studies should be documented and considered when establishing the facility's environmental monitoring programme.

We use The test method for this in AS ISO 14644.3 Method B.3 (Determination of airflow direction and visualisation testing in cleanrooms). This Method uses tracer particles, like aerosol, to observe/ track/record air flight movement in any clean room or cabinet. Opira can help design custom maintenance and testing programs specifically for your needs.

Our technicians are NATA-endorsed to carry out certification of your Airflow visualisations (smoke testing) according to the relevant standard AS ISO 14644-3, Method B.3 (Determination of airflow direction and visualisation testing in cleanrooms)

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