Eugia US Manufacturing LLC. is a subsidiary company of Aurobindo Pharma. It is a US-based independent pharmaceutical company focused on generic sterile injectables, hormones, oncology and ophthalmic medicines to cover the market globally.

Location: East Windsor, New Jersey (USA)

Works with: Scan 100 / ScanStation 300, real-time incubator and colony counters

Mr. Nilkantha Banerjee, Head of Microbiology, and his team offer a **ScanStation** testimonial exploiting the benefits of integrating the **ScanStation** into the Pharmaceutical industry.

How does automating microbiological analyses with ScanStation improve your laboratory 21 CFR compliance?

"Based on my review of the past 11 years data of the FDA Inspection Observations, the top 5 FDA 483 given for CFR violations in Microbiology were:

- **21 CFR 211.160(b) Scientifically sound laboratory controls,**
- **21 CFR 211.113(b) Control of Microbiological Contamination,**
- **21 CFR 211.110(a) Control Procedures to monitor and validate performance,**
- **21 CFR 211.165(a) Testing and release for distribution,**
- **21 CFR 211.63 Equipment Design, Size and Location.**

The highest number of observations were given for 21 CFR 211.160 (b). **Scientifically sound laboratory controls. ScanStation 300 can mitigate these observations with early detection**. The plates are read every hour, giving real-time colony counts with pictures. This robotic incubator will ensure that data integrity is followed with its 21 CFR Part 11 compliant software and ensures there is no data falsification. Data assurance is achieved through the review and approval process. ScanStation 300 is greatly improving laboratory 21 CFR compliance and control. **I believe ScanStation is revolutionary for the pharmaceutical industry**."

Nilkantha Banerjee - Head of Microbiology, **Eugia US Manufacturing LLC.**

Eugia US Manufacturing LLC is a generic injectables company and its mission is to produce affordable products to solve people health issues. The facility manufactures generic injectables products to cover the market globally. Eugia US Manufacturing LLC. was the first company in the United States to introduce the **ScanStation**, a real -time incubator and colony counter, in the pharmaceutical industry. Environmental Monitoring samples from Aseptic Filling Area classified as ISO 5 / Class 100 / Grade A are analyzed to guarantee environmental control and monitor product quality.

Why use ScanStation?

How did you hear about ScanStation? And why did you feel the need for automation?

Nilkantha Banerjee: "I discovered **ScanStation** in 2015 through my personal research when trying to find equipment that can automate processes in pharmaceutical microbiology. I heard that this equipment was being used in the food industry, but I wanted it to be incorporated in the pharmaceutical industry. I introduced **ScanStation** in the US pharmaceutical industry in 2019."

"I believe automation is needed to mitigate violations with 21 CFR 211 by allowing real time analysis of plates during the incubation process."

Nilkantha Banerjee

How does the ScanStation change your work?

> **“ScanStation** is very useful for understanding when the first colony appeared and on which location of the plate. It is important, especially for a plate with fungus.**”**
>
> **Nilkantha Banerjee**

Nilkantha Banerjee and his team: “ScanStation complies with CFR providing real-time data. It increased **traceability** and **reliability** of data. Early detection of presence of organisms in critical areas allows for early remedial actions for products, preventing **monetary loss,** and **saving brand value.**

We are **monitoring** all our **ISO 5/ Class 100/ Grade A EM** plates in the **ScanStation**. The acceptance criteria is less than 1 CFU. If a colony appears, we can notify the required personnel and start investigation to find the root cause. If microbial growth begins in these plates before our sterility results are obtained, it is crucial to halt the subsequent levels of manufacturing and product distribution. This applies to products that were manufactured before, during and after this EM monitoring occurred. This is essential for **operational safety and compliance** with regulations and the data obtained adheres to 21 CFR Part 11 compliance, ensuring an **Audit Trail** and preventing any possibility of **data falsification**.”

The feature that I like the most is that the **ScanStation** is a **real-time incubator** and **colony counter** and it allows to take **corrective actions in a timely manner if needed.**

It gives us the **“back in time video”**, which we can check during the incubation or even after.

ScanStation hardware and software are very user friendly.**”**

How was ScanStation introduction into your workflow?

Nilkantha Banerjee and his team: “We validated the **ScanStation** as per our internal validation program. We did not have to change our usual protocol. We use the same media for all our incubators.

ScanStation is used **daily** for **ISO 5 / Class 100 / Grade A Environment Monitoring**. We use the “Result & Approval” module which allows a dual validation by two different Microbiologists. It brings to us **data accuracy** because we check the plates manually and compare with the **ScanStation** count during the review and approval process. If the release of plates falls on a weekend or holiday, the review and approval happen on the next working day. However, the colony counts and images automatically stop after the incubation period ends.**”**

How do you manage the traceability of your samples?

Nilkantha Banerjee and his team:
“The **ScanStation** helps us to keep **traceability**. We really like this system because of our core values: **honesty, integrity and transparency** are met. We feel very comfortable of having implemented the **ScanStation** in our microbiological workflow. Because after all, we all work for patient **safety** and **quality medicine.** To trace our samples, we use the **unique ID number** given by the ScanStation (Plate ID No) and we write it down on our test data sheet.**”**

Protocol of analysis

Environmental Monitoring (EM) for ISO 5 / Class 100 / Grade A on settle plates and air sampling plates.

- Number of samples per day: 100 or more
- Microorganisms analyzed: Environment Isolates
- Medium used: Soyabean Casein Digest Agar (SCDA)
- Incubation time: 120 hours (5 days)
- Incubation temperature: 20-25 °C or 30-35 °C
- Program used (pre-set /custom): ScanStation Pre-set

Why choose Interscience?

Nilkantha Banerjee: “We chose Interscience because of its **innovative technology**. Interscience is **an innovator** that was able to create **revolutionary equipment in the microbiology field.”**

Nilkantha Banerjee: “The above testimonial is strictly my views based on my experience and does not represent the views held by the company with which I am affiliated.**”**