



# Visual Inspection Knapp Kit

By Gaurav Dakshini.

# Welcome To World of Success



It's time to evolve else get ready  
to dissolve



"The Fourth Industrial Revolution is not just about technology. It's about the Sync of technology with human skills. The real challenge is closing the skill gap—not just adopting the tools." -Gaurav Dakshini





# About Gaurav Dakshini

Confianza Technologies LLP

Confianza Pharmazon and Skillup to Scaleup Mission

Gaurav Dakshini is an accomplished professional with an MBA in Business Analytics, B.E Instrument & Control, PMP® certified professional and Authorized training Partner by PMI, demonstrating his commitment to excellence in Pharma/Biopharma Industry. With an impressive track record spanning two decades in pharmaceuticals and biopharmaceuticals, he's a visionary and industry leader.

Gaurav is renowned for his expertise in Data Analytics, Project management, Automation, Instrumentation, Validation & Sterile Engineering. inspiring and guiding others to achieve excellence in this dynamic field. His journey reflects a remarkable rise from an Engineer to C-suite leadership, embodying the principles of determination innovation, and leadership.

Gaurav Dakshini's legacy is marked by empowering individuals to reach their full potential in the pharmaceutical industry.

# Why

## Skillupto Scaleup with Gaurav Dakshini

### 20+ years

of experience in  
pharma and bio-  
pharma



### NMIMS

MBA in Business  
Analytics



### PMP (Authorized Training Partner by PMI)

Certified  
Professional



### Best Seller book

Author of Amazon  
#1 Best Seller book



Founder of the  
"Skillup to  
Scaleup"  
movement



### Confianza Pharmazon

One Platform,  
Unified Pharma  
Solutions



# Trained 500+

Pharma professionals in Data Analytics, PMP  
Certification, CGMP, AI/ML in Pharma, and more

# 10 million

Committed to upskill 10 million pharma &  
biopharma professionals

# About

## Confianca Technologies LLP



Confianca Technologies LLP is committed to support the pharmaceutical and biopharmaceuticals Industry through our High Quality Products and Services, including :

- Visual Inspection Knapp Kits (manual & automated qualification)
- Sterile Cleanroom Consumables (coveralls, sleeves, hoods, goggles, wipes, etc.)
- QC & Microbiology Consumables
- Automation Solutions (Vision Systems, Vial Counting, Tray Management, Label/Seal Verification)
- Cleanroom & Production Accessories (SS trolleys, sterile mopping tools, thermal paper rolls, IPA wipes)

We specialize in delivering GMP-compliant, audit-ready products that help pharma teams improve operational reliability, strengthen contamination control, and enhance efficiency across shop-floor and QC environments.

Our goal is to ensure our clients have access to reliable, validated, and compliant products that support safe and efficient pharmaceutical manufacturing.



# Who we are?

We are the leading platform dedicated to delivering cutting-edge pharma solutions for Pharma/Biopharma. Our commitment is to empower pharmaceutical and biopharmaceutical industries with the tools and innovations they need to thrive in an ever-evolving world. Driven by our core values of agility, integrity, responsibility, and empathy, we strive to be a trusted partner in the journey toward a sustainable and prosperous future.

# What we do?

We provide an extensive range of high-quality pharma products, services, projects and trainings tailored to meet the unique needs of the pharma and biopharma sectors. With a focus on agility and sustainability, we ensure reliable and efficient delivery, enabling our customers to achieve their goals and transform their industries. By 2030, our mission is to positively impact the lives of 10 million customers, offering solutions that drive progress and innovation.

# How we do?



C.A.R.E.S. stands for:

1. Customer Needs Identification (Understanding Your Needs)
2. Assessment & Proposal Creation (Tailored Proposal Creation)
3. Review & Finalization (Proposal Finalization)
4. Project Execution
5. Successful Handover

# Our Vision, Mission and Values



## **Vision:**

To be world's leading platform for Pharma Innovations, Empowering Customers to transform their industries and create better future.

## **Mission:**

To offer an extensive range of High Quality Pharma Products, Services and Projects while ensuring agile, reliable and sustainable solutions that empower 10 million pharma/biopharma customers by 2030.



## **Values:**

Agility, Integrity, Responsibility, Empathy

# The Pain

## The Challenges of Operating a Successful Business in the Pharmaceutical Industry

### Inconsistent Defect Detection by Inspectors

- Different inspectors detect different defects → no consistency.
- High variation in sensitivity leads to batch rejection or false acceptance.
- Difficult to prove inspection capability during FDA/WHO audits.

### High Cost of Rework & Batch Investigation

- Missed defects → market complaints or deviation investigation.
- False rejects → large volume of re-inspection work.
- Increased cost of manpower and delayed batch release.

### Audit Observations Due to Weak Documentation

- No validated defect library → auditors question inspection robustness.
- Missing records of inspector qualification.
- Lack of USP <790>/<1790> compliance evidence.

### Unvalidated or Inconsistent Defect Kits

- Home-made defect units are unreliable and non-standard.
- No particle sizing or qualification → inspectors learn incorrectly.
- Lack of defect categorization (accept, reject, grey zone).

### No Automation Support or Monitoring

- Fully manual process → no real-time monitoring of performance.
- No digital logs or traceability in booth operations.
- Hard to integrate with automated inspection systems for hybrid workflows.

### Non-standardized Booth Designs from Vendors

- Many booths fail to meet cGMP or 21 CFR Part 11 expectations.
- Poor-quality lighting, incorrect backgrounds, or unstable lux calibration.
- No documentation support during compliance audits.



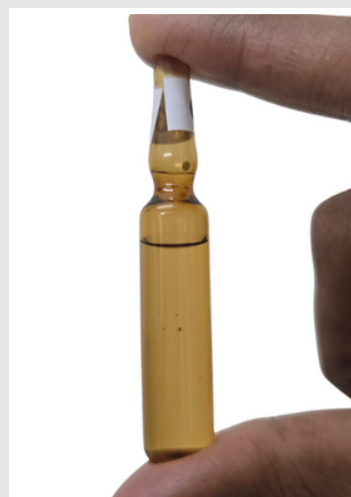
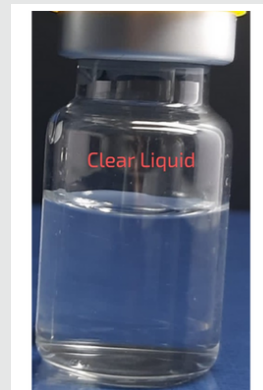
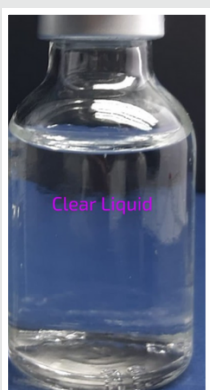
## ■ OUR CLIENTS



# Visual Inspection Knapp Kit

Knapp Kit, Manual Visual Inspection Kits, Particles, particulate Matters

Manual Visual inspection kits (Liquid and Lyophilized formulation with pack style of Vial, Cartridges and PFS), Knapp kits for Manual and Automatic visual inspection machines, Particulate matters of different micron size range at very competitive price.



# ■ Visual Inspection Knapp Kit

## Description

We are dealing with preparation of high standard Manual Visual inspection kits (Liquid and Lyophilized formulation with pack style of Vial, Cartridges and PFS) , knapp kits for Manual and Automatic visual inspection machines , Particulate matters of different micron size range at very competitive price. Kindly go through the attached catalogue for further details.

We are also offering the below services:

- Quality product with cost effective and timely deliverable
- Audit supportive documents with certificate of particulate matter
- Free replacement of any particle or containers, it may happen during transport.
- Audit response support – Requirement basis.
- Particle/Fibers sizing with certificates as per USP guidance and requirements.
- Onsite and Offsite Training on Visual inspection topic.

### 1.0 Defect description:

- Each particle & Fiber defect shall be created by highly trained and qualified technicians by using real source of Primary packaging material (PPM), Material used for machine parts/product contact part, Filter and garments used in Aseptic area.
- Each particle shall be washed and dried before using.
- Each particle shall be measured through a (3 dimensional) high resolution & high density digital microscope.
- Each particle shall be packed with a suitable slide (upper & Lower) or suitable air tight container.
- Technical team of Confianza Pharmazon shall guide to your team to seed the particle inside the container or any other type of queries.
- It is recommended to have Terminal sterilization of containers for longevity of kits.

# ■ Visual Inspection Knapp Kit

## Description

### 2.0 What you will get:

- Defect kit shall be properly packed in a hard corrugated box.
- One UV torch for defect number identification (Complimentary as free of cost).
- Master Certificate of each defect kit.
- Probability of detection (POD) evaluation sheet (Each container 10-time inspection).
- Free replacement of defect container upon found non-viable of defect (Occasionally it happens during transportation).
- Any type of regulatory queries on kit (Online support to be provided by experts 24 X 7).
- KIT expiry certification: 2 to 3 Years (Based on Formulation).

### 3.0 How Confianza Pharmazon is better than other Global supplier:

- One Day training by qualified visual inspectors at Confianza Pharmazon lab.
- Longer self-Life.
- Technical support and special kit handling training at Confianza Pharmazon lab.
- Particle/Fibers sizing with certificates as per USP guidance and requirements.
- Quality product with cost effective and timely deliverable
- Audit supportive documents with certificate of particulate matter

# ■ Visual Inspection Knapp Kit

## Services



- Fabrication of known size certified Glass Particles, Metal Particles, Black Particles & White Particles with different micron size range with advance technologies.
- Fabrication of known size certified Black Fiber, White Fiber with different micron size range with advance technologies.
- Manual Visual inspection Defect Library Kit, Training Kit and Qualification Kits preparation and authentication with qualified visual inspectors
- Knapp Kit for Automatic Visual inspection machine qualification.
- Training on Visual inspection Techniques such as handling of different formulations during visual inspection.
- Online and Class rooms Trainings on Visual inspection techniques, Visual inspector qualification programme with Guidance like USP chapters 790 and 1790.
- Fabrication of Particulate Matters such as Glass Particles, Metal Particles, Black Particles & White Particles, Black fibers and White Fibers with different micron size range:
- Known size certified Particulate matters are used to train the visual inspectors for identification of particulate defects during the routine visual inspection of products to ensure the products are essentially free from particulate matter as Visible particulates in injectable products pose a risk to patient safety.

## Particulate Maters includes:

Particle/Defects	Size Range (µm)	AvailableSize
Clear Glass	50+	As Specified by Customer
Amber Glass	50+	As Specified by Customer
Metal Particle	50+	As Specified by Customer
White Particle	50+	As Specified by Customer
Black Particle	500+	As Specified by Customer
Black Fiber	500+	As Specified by Customer
White Fiber	500+	As Specified by Customer
Any Color particle & Fiber	500+	As Specified by Customer
Hair fiber	500+	As Specified by Customer





# ■ Visual Inspection Knapp Kit

Manual Visual Inspection Defect Library kit,  
Trainings and Qualification kit

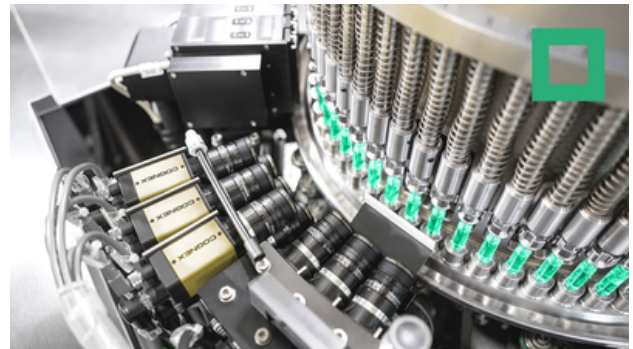


- We design different kind of qualification kits for Visual inspectors' qualification and provide the following:
- Defect Library Kit of different types of defects Training
- Kit with Defects and Good Containers
- Qualification Kits with Defects and Good Containers for effective visual inspector qualification program
- Different formulation like clear solution, color solution, oil base medium in Clear and Amber glass containers.

Defect Types in Training & Qualification Kit	
Critical	Wrong solution filled, Crystallization, Wrong container closure, Open Seal, Damage rubber stopper, Crack, Broken etc.
Major	Particulate Matters
Minor	Cosmetic Defect, Cap related defects etc.

## Knapp Kit for Automatic Visual inspection machine qualification.

- We designed the Knapp Kit which is used for the qualification of Automatic visual inspection Machines.
- These kits include components to identify defects such as cracks, particulate contamination, and seal integrity issues.
- Knapp Kit a specialized toolkit designed to facilitate visual inspection.





# ■ Visual Inspection

## Knapp Kit

Training on Visual inspection Techniques such as handling of different formulations during visual inspection.



- Training on Visual inspection techniques includes the below:
- Tyndall Lighting
- Supplement Inspection and selection approach
- Risk Assessment on visual inspection techniques
- Probability of Detection (PoD) Principles
- Reassessing Size Threshold and Other
- Particle Characteristics that Define Particle Visibility
- Inversion and swirling of vials.
- Lux Intensity for Clear and Color formulation
- Duration of inspections and Eye rest approach
- Acceptance Quality Level for Critical, Major and Minor Intrinsic and Extrinsic materials and probable sources

## Online and Class rooms Training on Manual Visual inspector and Automatic inspection qualification program

Training is provided on qualification program to qualify the visual inspectors for better understanding on defect detection during routine visual inspection. Each unit was visually inspected to ensure that no unexpected visible background particulate could be detected inside the units

- Guidance and Training on Manual Visual inspection Qualification Program
- Guidance and Training on Automatic visual inspection machine qualification
- Decision Tree on Routine inspection results and Qualification Program
- Particulate matter handling for Probability of Detection
- Qualification Kits and Knapp Kits understanding
- Guidance on Defect prevention: A lifecycle Approach
- Training on Case Studies and USP chapters such as 790 & 1790



# ■ Visual Inspection

## Knapp Kit

### Manual Visual inspection Booth with 21 CFR Part 11 Compliant:

Visual inspection booth is used during the inspection process which provide the environment to qualified visual inspectors to identify the particulate matters and other defects



- 21 CFR Part 11 Compliant Reports
- Visual inspection booth provided with below
- Mention requirement:
  - Black and White
  - Background Working zone
  - Height identification High
  - Standard Luminous facility
- Audio buzzer for operator during eye rest
- Rejection storage drawer with defined compartment Installed
- Magnifying lens
- Online Lux measurement
- Height adjustable facility
- Other specification as per customer requirement



# Confianca<sup>TM</sup> Pharma-zon

One Platform, Unified Pharma Solutions<sup>TM</sup>

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