Gloved Fingertip Sampling: Lecture and Practice

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Learning Objectives

At the end of this session, you will be able to:

1. Differentiate between the NAPRA Model Standard requirements and best practice recommendations for personnel gloved fingertip sampling.
2. Describe the best practice integration of initial and subsequent gloved fingertip sampling.
3. Determine the importance of using personnel sampling to validate a compounders ability to perform hand hygiene and garbing tasks and maintain sterility throughout the compounding process.
4. Practice gloved fingertip sampling using 100 mm settling plates.

Initial Training and Assessment - Compounding Personnel

The initial training and assessment program for compounding personnel must have the following components:

- Reading and understanding the policies and procedures related to compounded sterile preparations (*see* Appendix 1);
- Theoretical training, with assessment covering various topics, including those listed in Appendix 3;
- Individualized practical training and assessment in the workplace clean room (*see* section 7 and Appendix 3); and
- **Assessment of aseptic techniques, based on gloved fingertip sampling (GFS) and a media fill test, for the various types of sterile preparations to be compounded.**

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Personnel Testing and Sampling

Objectively gauges aseptic technique and associated work procedures using:

- Media fill testing (MFT)
- Gloved fingertip sampling (GFS)
  - initial (IGFS)
  - subsequent (SGFS)– after media fill
- And as a best practice, surface sampling of the direct compounding area (DCA) during simulated or actual compounding circumstances.

Initial Assessment

Personnel **must pass GFS and a media fill test** before working in the compounding area for non- hazardous sterile products.

Any compounding employee who has successfully completed the initial workplace training and assessment program may begin work in the compounding of sterile preparations.

Employees with limited experience may require additional training and supervision.

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Ongoing Competency – Compounding Personnel

- See Appendix 3 in NAPRA Model Standards for training **musts**

NAPRA Model Standard	Frequency
Practical test in the clean room (including GFS and media fill test)	Once a year for low or medium risk Two times a year for high risk

CCR Best Practice Recommendation

Two times a year for low or medium risk

Quarterly for high risk especially if performing sterility testing on high risk

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Who **must** be tested?

- New staff who will perform sterile compounding
- Existing staff who perform sterile compounding
- Pharmacist who never compounds but supervises pharmacy technicians and assistants if there is any possibility that they may compound

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GFS – Gloved Fingertip Sampling

Initial Gloved Fingertip Sampling

Subsequent Gloved Fingertip Sampling

Gloved Fingertip Sampling

- Initial Qualification (three consecutive occurrences)
  - Hand hygiene and garbing procedures are performed
  - Sterile gloves are donned then the sample is obtained
  - **Before application of sterile 70% isopropyl alcohol:** Disinfecting gloves with sterile 70% isopropyl alcohol immediately before sampling may lead to false negatives.
- Subsequent
  - Another sample is **obtained after the media fill test** making sure that the employee has not applied sterile 70% isopropyl alcohol to his or her gloves in the minutes before sampling

Purpose of IGFS

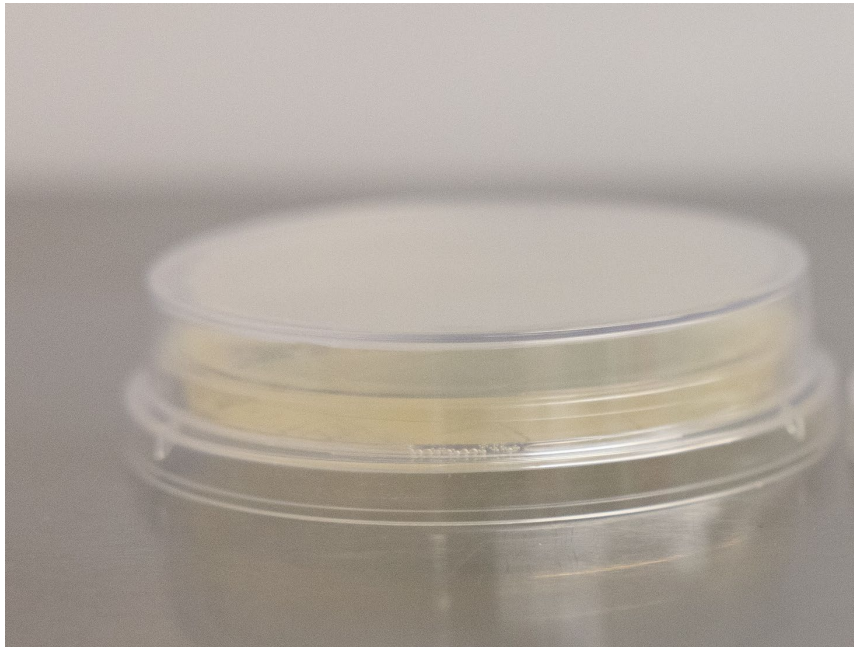
To ensure that personnel perform hand hygiene properly and put on sterile gloves without contaminating them

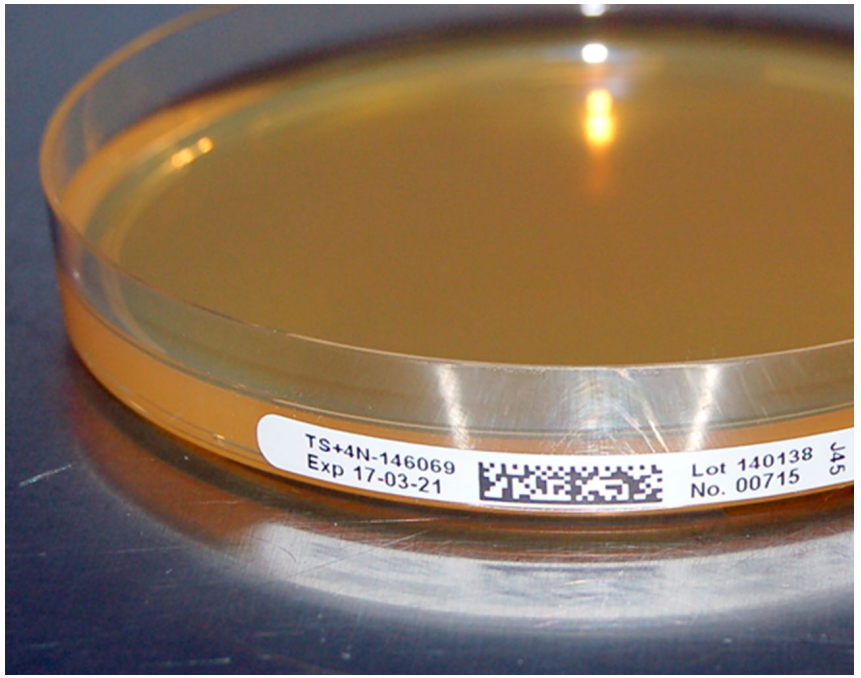
Purpose of SGFS

To verify that staff can keep the bioburden on their gloves low during compounding

NAPRA Model Standards GFS

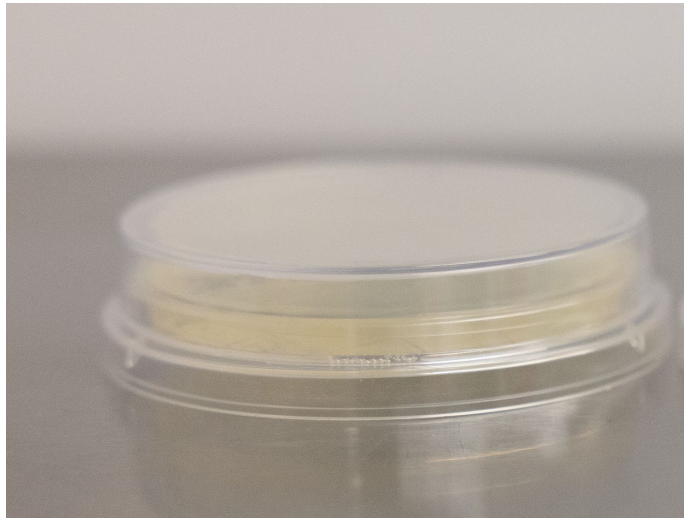
- Says to use tryptic soy agar (TSA) contact plates with lecithin and polysorbate (neutralizing agents)
- CCR Best Practice: Use 100 mm settling plate which accommodates rolling of fingers and the thumb without having to overlap

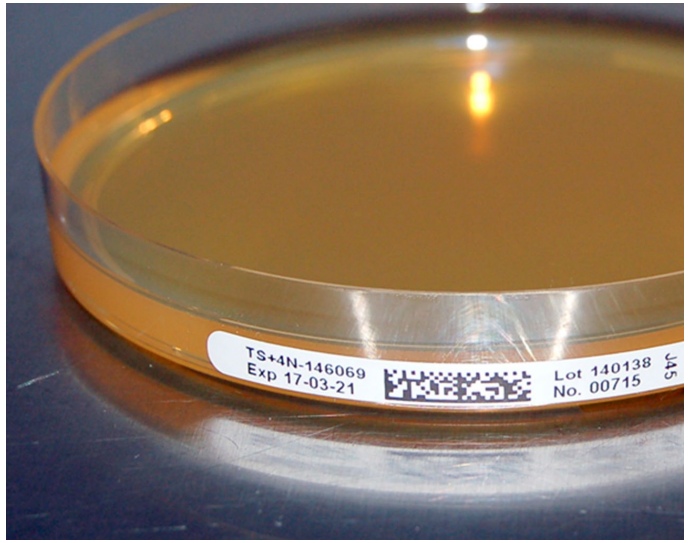




Types of Plates

- Settling Plates
  - Concave
  - Used for: GFS, viable air sampling (depending on sampler)
  - Size ~100 mm
- Contact Plates (aka RODAC® plates)
  - Convex
  - Used for: surface sampling, viable air sampling
  - Size ~55 mm





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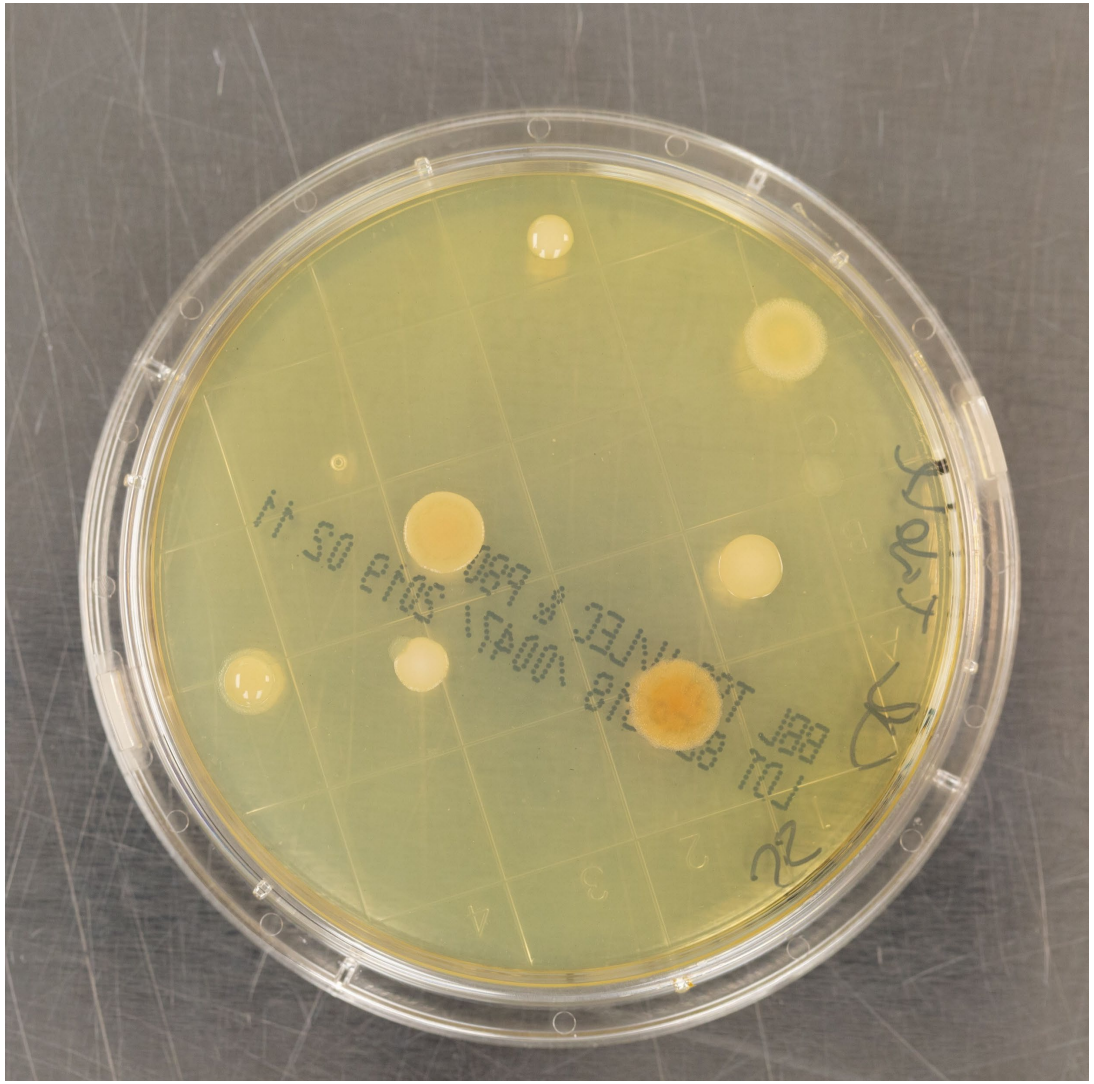
Label Plates

- Type of sample: IGFS vs SGFS
- Compounder's name
- Left or right hand
- Collection date
- **Document on the edge on the plate in order to not block the agar to help with counting colony forming units.**



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NAPRA Model Standards-GFS Procedure

- The assessor obtains;
  - thumbprints and prints of gloved fingertips from both hands of the employee
  - asking the employee to gently press and roll each thumb and fingertip on the agar in the contact plate (one agar plate for each hand)
- When the sampling is complete, the gloves must be taken off and thrown away, and hand and forearm hygiene must be performed.

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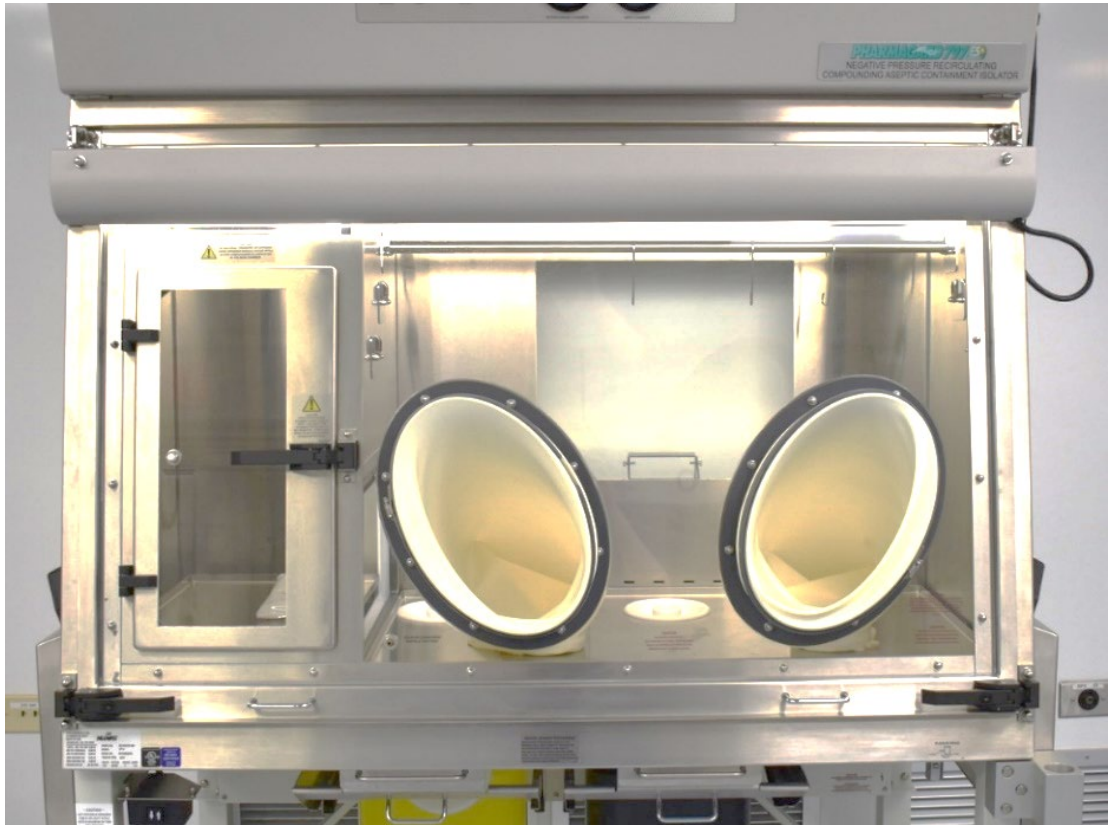
Where are IGFS samples collected?

- Collect where gloves are donned
  - Segregated compounding area
  - Clean room (NAPRA MS require donning sterile gloves in clean room)
  - In the CAI/CACI regardless of where it is located

Sterile gloves are donned over the CAI/CACI gloves and sampled from inside the PEC.



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Incubation

- Per NAPRA Model Standards
  - Between 30°C and 35°C
  - Must be read within 48 to 72 hours

CCR Best Practice:

- Phase 1: Incubate inverted at 30 to 35 °C for at least 48 hours, not to exceed 72 hours
- Phase 2: Incubate inverted at 20 to 25 °C for at least 5 days, not to exceed 7 days
- Read at end of 1st and 2nd incubation

Two-Phase Incubation

- Different microorganisms grow at different temperatures.
- Must expose them to temperatures they need otherwise, we may miss growth of some microorganisms.
- Microorganisms typically found in clean rooms need dual incubation at 30 to 35 °C and 20 to 25 °C.

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Action Levels

For each employee, **a negative result (0 CFU) must be obtained three times** for the **first GFS** (obtained after sterile gloves are put on) before the employee can be permitted to compound sterile preparations.

For the subsequent test occurring after media fill, the total **CFU count for both hands** must be **no more than 3 CFUs**.

If the result on any GFS after a media fill test **is more than 3 CFUs**, the sterile compounding supervisor is prompted to investigate the employee's work practices, procedures, use of disinfectants, etc.

Reading GFS Samples

- Who reads and how are they trained and qualified?
- Use a negative reference sample to compare
- *Hint:* always visually inspect media before use, since any irregularities present before will be read as a failure after incubation
- Carefully remove from the incubator.
- Good light, white and dark backgrounds

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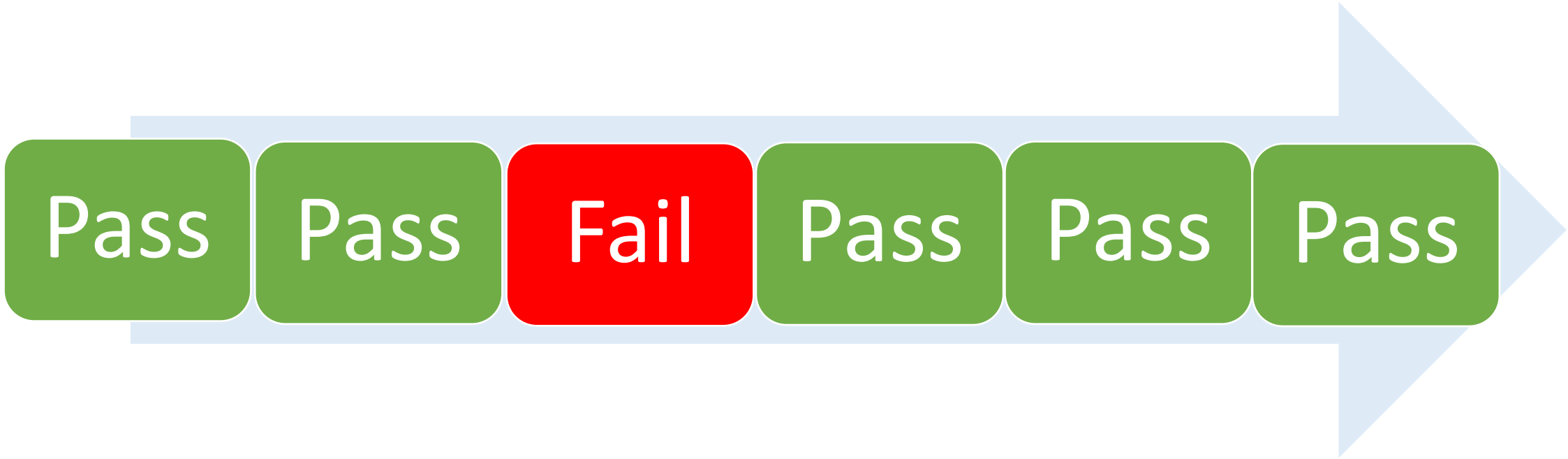
Do staff have to pass 3 consecutive IGFS?

- NAPRA Model Standards require staff to pass 3 GFS
- **CCR recommends 3 *passing in succession* to show competency**



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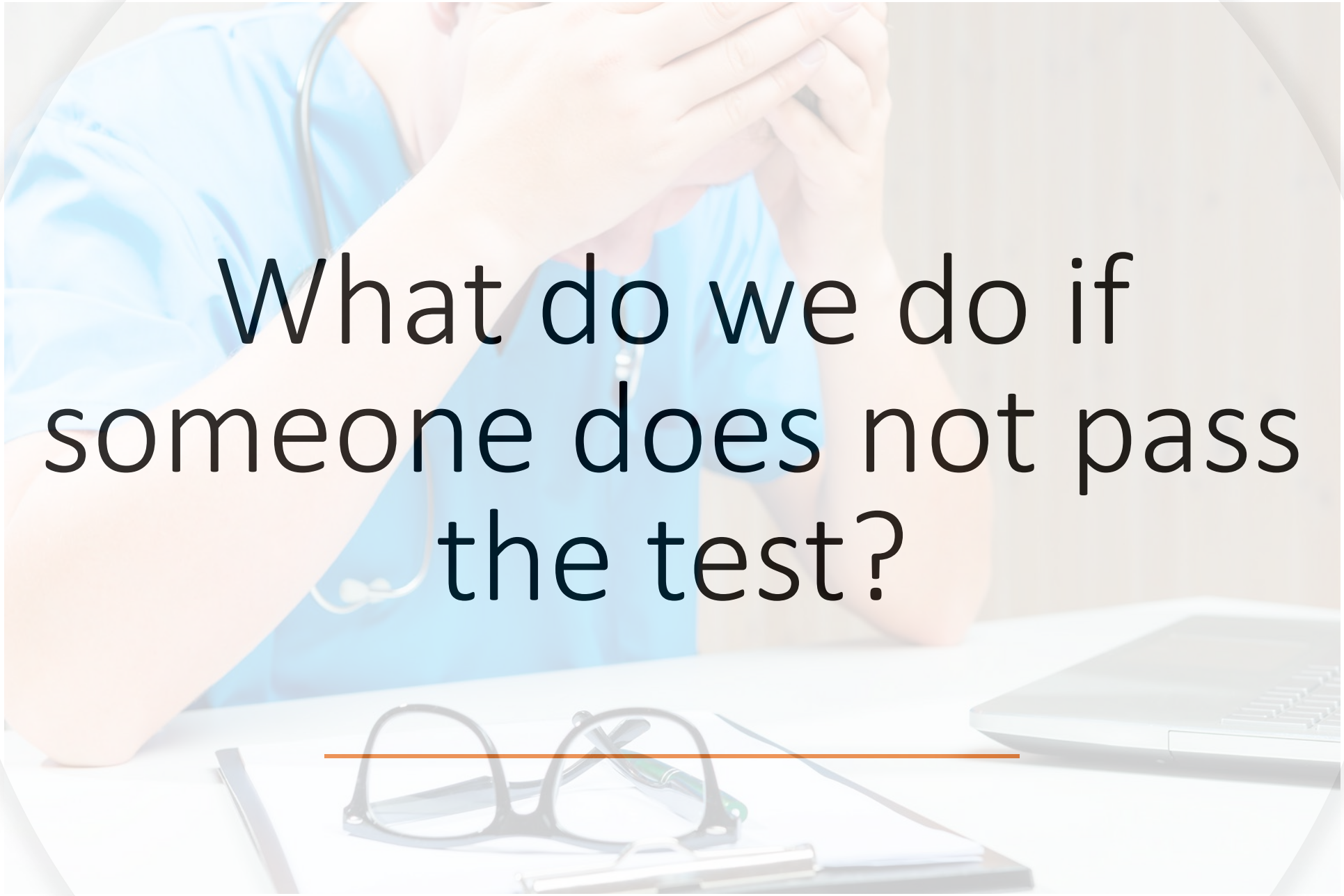
Summary of GFS

Test	IGFS	SGFS
Who	New Compounders	New Compounders and Existing Compounders
When	Before beginning to compound for patients (three times)	After MFs or compounding, perform randomly or at end of shift
Where	Where gloves are donned	In PEC
Action Level	> 0 CFU (total for both hands)	>3 CFU (total for both hands)

GFS and Media Fill Documentation

- Name of person evaluated
- Evaluation date and time
- Media and components used to include their manufacturer or supplier
- Expiration dates and lot numbers
- Starting temperature for each interval of incubation
- Dates of incubation
- Results of evaluation and corrective actions
- Name or other identification of the observer and the person who reads and documents results



What do we do if someone does not pass the test?

Failures

Compounding personnel who fail the written or practical assessment must immediately stop sterile compounding and redo their training.

Cleaning and disinfecting personnel who fail the practical assessment must immediately stop cleaning and disinfecting and redo their training.

An individual may resume assigned duties after passing the elements previously failed.

In case of repeated failures, a decision must be made regarding permanent termination of sterile- preparation compounding or cleaning and disinfecting activities.

Retraining and resampling/retesting

- Train – repeat didactic training and testing, practice with simulated ingredients
- Review – go through competency assessments
- Teach back – ask the compounder to explain hand hygiene, garbing or aseptic technique principles to you and then perform them
- Observe and provide feedback
- Resample/retest in the next compounding shift
- Repeat two more times in upcoming shifts

Questions?

Time to practice!

- Demo
- Don sterile gloves
- Practice in groups of 2

Closing Points

- Initial GFS is required by NAPRA Model Standards and must be performed by new compounding employees to ensure staff can perform hand hygiene and garbing and don sterile gloves without contaminating them.
- This type of sampling is the only time ZERO CFUs is required.
- Subsequent GFS testing provide objective data that verifies a worker can maintain acceptable conditions for aseptic compounding through proper hand hygiene and garbing, material handling, and aseptic technique.
- CCR recommends to perform more frequently and at unscheduled times to better assess staff.

References

- NAPRA Guidance Document for Pharmacy Compounding of NonHazardous-Sterile Preparations, National Association of Pharmacy Regulatory Authorities, November 2016.
- USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations, The United States Pharmacopeial Convention, 2023
- Retrieved from Chegg Lab Growth Patterns Flashcards. Retrieved on July 6th, 2023.
- NAPRA Model Compounding Competencies for Pharmacists and Pharmacy Technicians in Canada.