CHALLENGE STATEMENT #07

1. Challenge Owner Index and Pseudonym

#07 – Capsule

2. Challenge Statement

We are a non-profit organisation that represents pharmacists professionally to provide Singaporeans with high quality pharmaceutical services. We conduct an Aseptic Compounding Course for healthcare staff, which teaches aseptic practices to be applied during sterile drug compounding in a cleanroom environment. However, training and assessment is manpower- and resource-intensive. Additionally, we face constraints in providing hands-on/practical training due to limited training sites. The course curriculum currently includes a theoretical component, supplemented by an online discussion of course materials. The National Pharmacy Strategy rolled out by the Ministry of Health (MOH) is pushing for the upscaling of sterile compounding standards nationally, through the establishment of GMP-certified (Good Manufacturing Practices) compounding facilities that will require highly trained personnel in order to achieve system benefits of safety, quality and efficacy of sterile compounded products. We are seeking a digital solution in collaboration with a restructured hospital Pharmacy Department to provide a structured and comprehensive program for hands-on training, practice, and assessment of aseptic compounding techniques to complement our Aseptic Compounding Course, which is open to participants nationwide. We will evaluate the proposed solution based on suitability to our needs, usability, increase in learner competencies and scalability.

3. About the Challenge Owner Organisation

The "Capsule" is the professional organisation representing pharmacists in Singapore. Today it is steered by an elected council comprising a president and 11 council members. Membership comprises of pharmacists practicing in the community, hospital, marketing/sales/distribution and academic sectors. The "Capsule" is a non-profit organisation. The mission of the "Capsule" is to "Maximise the contribution of pharmacists to the healthcare of Singaporeans". To this end, the organisation has adopted a two-pronged strategy - to upgrade pharmacists professionally and to reach out to the public through health education programs, in order to provide Singaporeans with high quality pharmaceutical services, which emphasise safe, efficacious, and cost-effective drug treatments.

4. Define the Challenge

Current Situation
Sterile drug compounding is a specialised skillset that is needed by healthcare workers, such as pharmacists, pharmacy technicians and nurses, who are working in certain settings that require the preparation of a medication in a sterile environment free from bacteria, viruses, and other potentially infectious microorganisms. The process involves aseptic techniques, which applies strict rules in practices and procedures to prevent the medicinal products from being contaminated with

pathogens, in order to minimise the risk of infections. Examples of sterile compounded drugs include medications that are administered through intravenous (IV) injections or infusions, or directly on/into the eyes.

The training process involves both theory and practical (hands-on) components, and it takes 3 to 6 months for each healthcare staff to complete the vigorous training program successfully and to be able to work independently. The theoretical aspects of the training program comprise of providing a holistic overview of working in a cleanroom environment, the types of potential contaminants and contaminations, what are the critical zones and surfaces of the medicinal product and environment, decontamination techniques, etc. The practical/hands-on aspects, on the other hand, involve the learners practicing proper handwashing techniques and how to put on personal protective equipment (PPE), including sterile gowns, gloves, headgear, and footgear; as well as practicing how to handle actual syringes, needles, ampoules and vials in a safe manner, yet without contaminating the items/products (**Figure 1**). A quick demonstration of the sterile compounding process involving aseptic techniques is available at: https://youtu.be/B-g_5WLffMM.
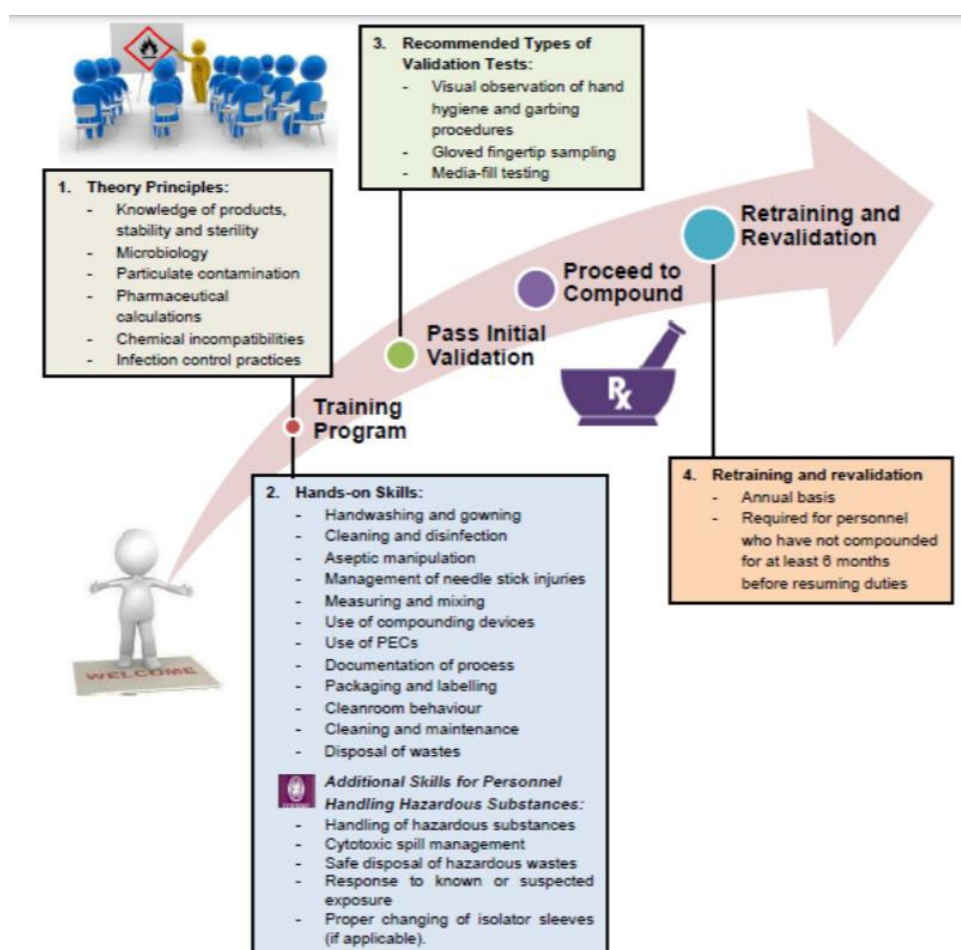

Figure 1. Training and revalidation requirements for sterile compounding.
Adopted from Ministry of Health Singapore[1].

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[1] Pharmaceutical Standards Working Committee. Guidelines for the Conduct of Sterile Pharmaceutical Services in Healthcare Institutions. Singapore: Ministry of Health; 2016. Available at: https://www.moh.gov.sg/docs/librariesprovider4/guidelines/guidelines-for-conduct-of-sterile-pharma-services-in-institutions.pdf. Accessed 14 Feb 2022.

Besides the cost of consumables for each trainee and session, there is also a need to cater for trainer manpower and the use of facilities/equipment for these exercises. All these training will culminate into a validation exercise and/or assessment in the hospital setting where the healthcare staff will simulate the preparation technique of different medicinal products using microbial growth media, which are then subjected to microbial testing (https://youtu.be/fND5I_A7wNM) to ascertain if the simulated products have remained uncontaminated in the course of the aseptic manipulation.

The training of the hands-on/practical components has always been left to the learner's institution to conduct in their own labs during operational hours, which impacted manpower, time and service delivery, and disrupted workflows. This process also led to variations in training practices among the different hospital institutions. Learners are often taught historical practices without understanding the rationale or principles behind the practices. Hence, there is a need to create a standardised hands-on training program that will allow learning and practice outside of physical facilities.

Past & Current Solutioning Efforts

The "Capsule" has been conducting an Aseptic Compounding Course for pharmacists and pharmacy technicians to cater towards national competency standards. This course is run yearly. Various hospital institutions send their healthcare staff working in the area of aseptic compounding to this course which comprises of online learning, which must be completed within 2 months of enrolment, followed by an online facilitated discussion to address participant questions. The e-learning content is split into 16 online lessons on theoretical aspect of aseptic compounding delivered by means of lectures, video demonstrations and interactive exercises (Table 1). Learners have the opportunity to learn at their own time and pace.

The Aseptic Compounding Course, however, has not been able to deliver hands-on training due to the lack of cleanroom facilities and trainer manpower. Hands-on practice for basic skills (e.g. gowning technique and basic aseptic technique) would typically take 2 to 3 hours per day for up to a week under the observation of a trainer. Thereafter the learner needs to be qualified by undergoing an aseptic technique validation, after which the learner will be qualified to learn the skills to compound the various types of products under the supervision of experienced staff. It may take between 3 to 6 months before a learner can compound independently.
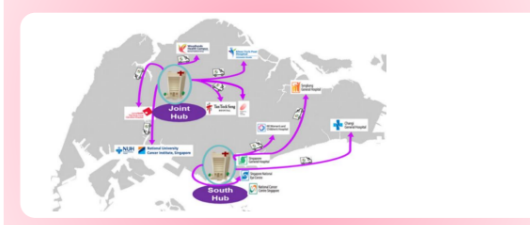
Table 1. Summary of Aseptic Compounding Course

Aseptic Compounding Course Information	Details
Target Audience	Personnel working in aseptic compounding areas (pharmacists, pharmacy technicians, nurses)
Topics Covered	- Engineering controls for sterile compounding - Personnel sampling metrics - Viable facility sampling metrics - Sanitisation of pharmacy-controlled environments - Aseptic technique and related work practices - Requirements and best practices for hazardous drug compounding
Content Mode	16 online lessons - E-lectures - Video demonstrations - Interactive exercises

Challenge / Gap / Unrealised Potential

It has always been a challenge to train and qualify staff in the practical aspects of aseptic compounding as it is a niche area of practice with limited number of experienced trainers and limited facility (cleanrooms and laminar flow cabinets) for training. Aseptic compounding is an essential service as it provides preparations that are not available commercially to patients for whom there is no commercially available options.

In addition, as part of the Ministry of Health's (MOH) healthcare transformation strategy towards a "smart nation", a National Pharmacy Strategy (NPS) has been developed[2]. Within the NPS, a national initiative in relation to centralising sterile drug compounding and distribution has been envisioned to enhance the safety, quality and resilience of the public healthcare sector at a system level with respect to sterile drug compounded products (**Figure 2**).

Re-design Supply Chain	3.1 Centralise sterile drug compounding and distribution	FY2021 (SGH) FY2022 (NCCS)

Click to return to Content page

Objectives — To achieve system benefits of Safety, Quality and Resilience for the public healthcare sector with respect to sterile drug compounded products

Hub & Spoke Model

First in Southeast Asia Hub-and-Spoke model in hospital pharmacy setting
Pharmacy compounding laboratory (hubs) will be built to PICS GMP standards and supply to compounded sterile products (CSPs) to other PHIs (spokes)
Two cytotoxic and non-cytotoxic hubs each
SGH and NCCS hubs at SHS will start operation from 2021 and 2022 respectively

Benefits

✓ Improved medication safety with automation and GMP certified Hubs, provision of readily usable dosage form including high alert medications
✓ Improved staff safety by leveraging on technology & reduce cytotoxic exposure
✓ Build system resilience & continuity
✓ Enable pandemic preparedness
✓ Build up compounding capability for Singapore
✓ Cost saving from lower headcount including nursing staff

Regulation of CSP (Under discussion)

✓ Enhanced regulation of category 2 CSPs to be manufactured in PICS GMP facility.
✓ Multiple different products combined into a preparation
✓ Multi-day/multi-dose prep (e.g. infusion pumps)
✓ New dosage form (e.g. preparation of eye-drops from injections) and/or
✓ Batch production (i.e. usage is anticipatory, no named patient at point of preparation)
✓ Other categories of CSPs will follow MOH guideline

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Figure 2. MOH's vision to centralise sterile drug compounding and distribution in Singapore. Adopted from the National Pharmacy Strategy[2].

Hence, there is a critical need to produce highly trained healthcare personnel in this area in order to provide system benefits of safety, quality and efficacy of sterile drug compounded products. We aim to provide an authentic learning environment and the experience of aseptic compounding through this solution so that learners will be operationally ready without being limited by the lack of resources and/or trainers.

The practical aspects of aseptic compounding training currently conducted by skilled trainers that can be ported over to the simulated learning space are:

    i.   Basic aseptic skills instruction and practice, in preparation for real-live aseptic technique validation in the cleanroom using microbial growth media; and

    ii.   Upscaling basic aseptic skills through training on compounding technique of specific products (e.g. eye-drops, infusers, cassettes etc).

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[2] Ministry of Health. National Pharmacy Strategy. Available at: https://www.moh.gov.sg/hpp/pharmacists/national-pharmacy-strategy. Accessed 14 Feb 2022.

We intend to collaborate with a restructured hospital's Pharmacy Department to co-develop a potential digital solution in a simulated environment that will provide a structured and comprehensive program for hands-on training, practice, and assessment of aseptic techniques to complement our Aseptic Compounding Course. The intended digital solution will be used first to train a batch of healthcare staff (i.e. pharmacists, pharmacy technicians) from the hospital. Once successful, this digital solution will be rolled out as part the Aseptic Compounding Course to train other healthcare personnel nationally.

5. Targeted Learners / Users

The digital solution is for healthcare staff/trainees/students in acute and community hospital settings who are working in the areas of sterile drug compounding requiring aseptic techniques and/or require such knowledge and skills. These include:
- *Trainers and/or Assessors* – They will use the digital solution to provide training and assess the learners. These include personnel who will train-the-trainer for the digital solution.
- *Learners* – These include healthcare staff (e.g. pharmacists, pharmacy technicians, nurses, etc), trainees (e.g. pre-registration pharmacists), students who are undergoing attachments (e.g. pharmacy students undergoing attachment rotations), and students in tertiary institutions as part of their curriculum (e.g. pharmacy and pharmaceutical sciences).
- *Administrators* – They will administer the training program and set up and/or perform simple troubleshooting for the digital solution.

Primary target number:
- Participants of the Aseptic Compounding Course as well as trainees in this restructured hospital's Pharmacy: ~ 30 per year

Secondary target number (these users will not be involved in the pilot study in this challenge):
- Potential users include students and trainees from the Pharmacy and Pharmaceutical Science Specialisations in universities and polytechnics, as well as Nursing trainees in this restructured hospital and other hospital institutions: ~300 per year

6. Solution Partner and Deliverables

We are looking for a Digital Solution Partner who has the technical knowledge and technology experience to build a personalised and adaptable learning solution in order to develop and implement a standardised sterile compounding and aseptic technique training program for a multi-hospital system with feedback for improvement. The partner must be familiar with the current and upcoming technologies that are able to provide a digital solution/innovation that will allow hands-on simulation environments and tools for training and assessment of knowledge and practical skillsets in compounding and aseptic techniques of medicinal products in a hospital laboratory setting. The solution should also provide an interface for educators/trainers to observe, review, assess and provide real-time feedback to learners. Furthermore, the partner must be experienced with techniques and technologies to be able to harness the training/learner data to provide real-time analysis of individual and group trends, as well as provide time-based predictions of learners' knowledge, skillsets, and competencies.

7. Expectations of Solution

The requirements for the digital solution are as follows:

- An automated teaching/training and assessment solution that allows learners to learn in a close-to-real-life environment without the need (or reduces the need) for human trainers.
- The solution should be able to be implemented online so that it can be accessible by learners at the workplace (hands-on components) and on-the-go (theories/concepts), as well as by multiple learners at the same time.
- Simulated environment must be equivalent to a real-life representation of a GMP-certified lab environment.
- Allow for both individual and group learning with the ability for learning interactions, so that learners can work together to identify potential patient safety issues, such as focusing on unsafe medication practices and errors, and selecting preventive strategies to reduce medication errors.
- Enable speech/dialogue management capabilities to allow learners to communicate effectively in the simulated environment, combined with recording and archiving capabilities for trainers to assess, identify trends and conduct feedback.
- Create an automated review and grading process of learner tasks and scenarios in an unbiased and comprehensive manner. The digital solution should be designed with the ability to record the learner's action and how the tasks are executed, as well as track the learner's progress and improvement with time.
- Provide real-time analysis and feedback that is personalised to the learner's approach to completing the tasks/scenarios.
- Create a user analytics-based interface that allows educators/trainers and administrators to keep track of both learner and system performance. The interface must be able to show data trends on learner performance with time and predict the competency levels of the learner based on past performance in both assessment and non-assessment scenarios.
- All data by and within the digital solution must abide by PDPA.
- Can be further adapted and expanded to allow educators/trainers to create and develop other content/scenarios in other healthcare fields/domains that is intuitive and responsive to learners' needs.
- Must be integrated and work seamlessly with IT systems within public healthcare sector (e.g. Wifi, intranet/VPN, internet. institutional IT security policies).
- Solution Partner must sign an NDA with the challenge owner and collaborator.
- All public dissemination and/or commercial use of the digital solution must acknowledge all parties involved (including challenge owner and collaborator).

8. Measures of Success

Selection criteria:
- Experience of Solution Provider in developing automated simulation teaching/training and assessment programs for hands-on/practical training components
- Product showcase and/or portfolio of digital environments to ensure that it fits our target audience(s) – note that actual product environment should be shown (not a poster/static portfolio)
- Quality of digital learning innovations done by Solution Provider
- Experience of Solution Provider with the IT systems in public healthcare sector
- Ability for potential digital solution to be integrated and work seamlessly with IT systems in public healthcare sector (including IT security policies)

- Comprehensiveness and adaptability of digital solution to cater towards trainers', administrators' and learners' needs
- Adaptability of learning content/scenarios beyond prototype
- Comprehensiveness of digital solution to provide grading, feedback and data analytics
- Potential for speech/dialogue management capabilities
- Quality of storyboard for a certain aspect of the sterile compounding process involving aseptic techniques, as shown at: https://youtu.be/B-g_5WLffMM (viewed from the perspective of the learner/user)

Evaluation criteria:
- Development of a digital learning solution that is learner-centric and user-friendly to both trainers and trainees
- Capability of digital solution to provide responsive feedback for learner improvement, which is both personalised to the learner and contextualised based on the learner's nature of work and their workplace
- Quality of digital solution and simulated environments/scenarios
- Ability for the simulated environment, tasks and scenarios to be adapted for various purposes (e.g. repeatable for learners to practice; items and environment can be updated with new products/devices/scenarios; and adaptable for assessment purposes and other domains)
- Digital access to learners with no constraints of time, space and resources (i.e. learners are able to learn at their own time and pace without being limited by the availability of trainers), but also in a fixed standardised environment for assessment purposes
- Ability to integrate seamlessly with the IT/digital ecosystem in the public healthcare sector as learners may be accessing this solution from work devices
- Optimisation of resources with minimal disruption to the current workflow of trainers
- Reduction in training costs (i.e. time, manpower and resources) in the mid- to long-term, with more learners being able to go through the training at their own time and pace without negatively impacting trainers' time and efforts
- An effective training strategy using the educational pedagogies set out in this project to maintain a standard level of best practices and operational standards with regards to aseptic compounding
- Interest in the solution by other companies/organisations (e.g. public and private sector organisations who are interested in adopting the solution for staff training in aseptic compounding)

Evaluation methods:
- Usability survey and trainer/learner feedback (quantitative and qualitative)
- Cost assessment and comparison between current teaching method and the proposed solution

Expected observable outcomes:
We envision better trainer and learner satisfaction with more interactive, engaging and collaborative learning that will enhance the training/learning experiences of stakeholders. These include:
- A solution that is able to provide standardised training of best practices and operational standards with regards to aseptic compounding
- Positive feedback from trainers and learners regarding their training program
- Less time pressure for trainers and learners
- Less confusion for learners as content is standardised (no trainer-to-trainer variability)

Expected measurable impacts and learning outcomes:
- Up to 25% reduction in trainer time
- Improvement in learners' knowledge and skills (based on assessment rubrics)

- Shorter induction period for new staff (up to 25%) as staff can learn/practice at own time and not be reliant on trainer availability