

NEW ACTIVITIES WITHIN A CLINICAL TRIAL MANAGEMENT UNIT: WHAT NEW RISKS FOR THE STAFF ?

3PC-023

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Background and Importance

Pharmaceutical personnel continually face occupational risks during clinical research, necessitating regular updates to address evolving activities like Advanced Therapy Medicinal Products (ATMP) and direct patient dispensation.

Aim and objectives



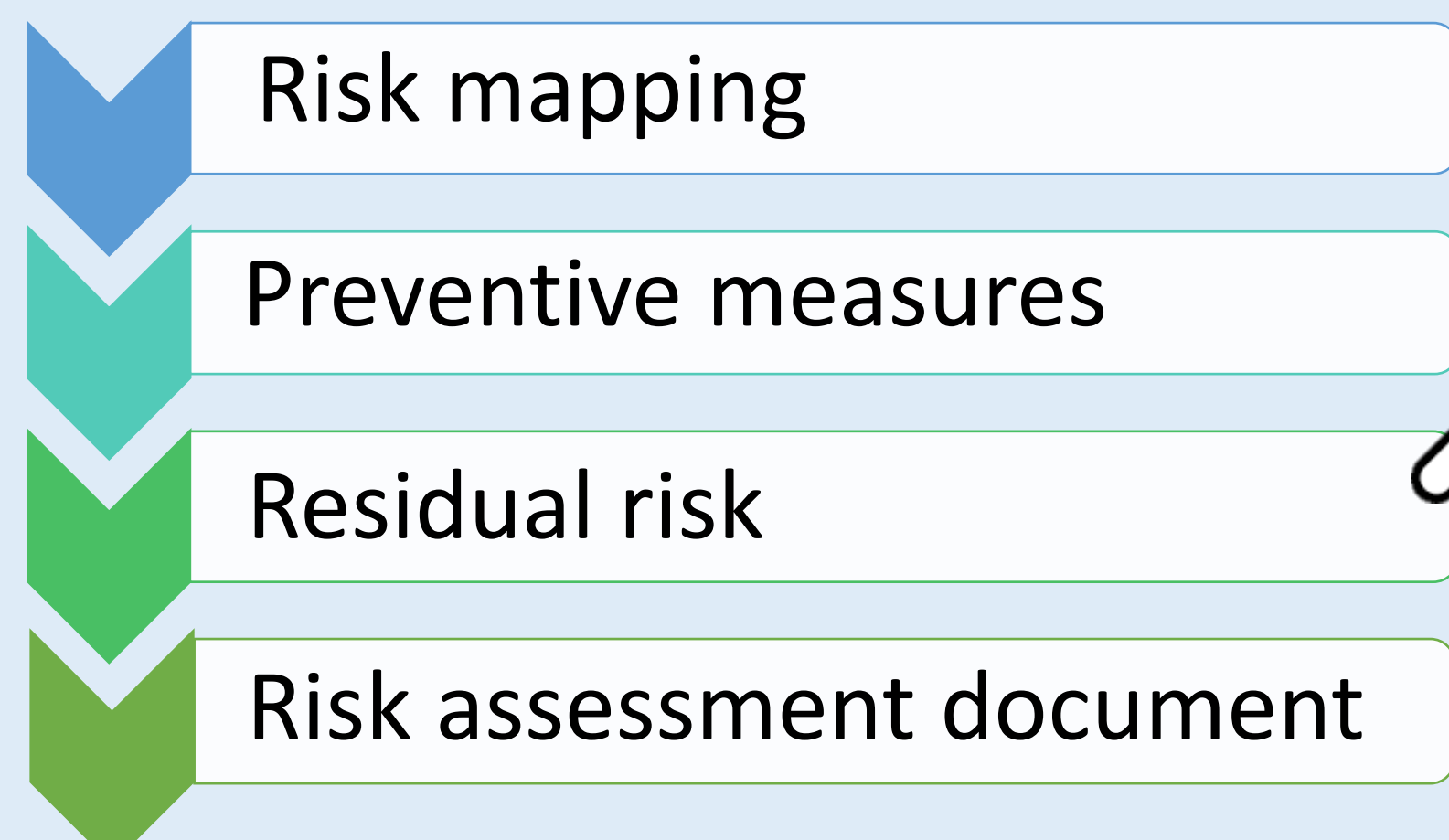
Comprehensively assess risks utilizing a risk mapping approach and implementing tailored preventive measures for effective mitigation.

Materials and Methods

Multidisciplinary



Pharmacists,
managers, risk
assessors



Criticality = severity x frequency x mitigation measures

Tolerable

Prevention measures already in place are sufficient

To be monitored
Preventive measures must be considered

Significant

Preventive measures must be planned

Very significant

Preventive measures must be applied immediately

Results

Risk mapping

9 novel occupational risks

Workplace hazards

Nitrogen handling

Burns
Explosion
Hypoxia

Travel associated

Experimental treatment delivery to patients and hospitals

Accident
Breakdown

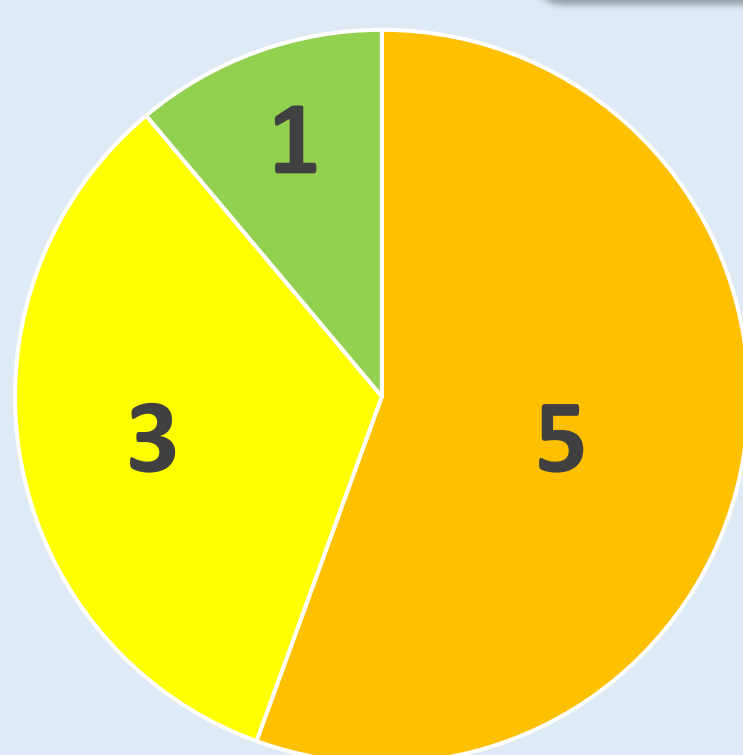
Biological

ATMPs : GMOs and cellular therapy

Biological contamination

Risks criticality

8 risks require prevention measures



■ Significant ■ To be monitored ■ Tolerable

Preventive measures

7 preventive measures identified

Individual protection equipment

- Individual Protection (oximeter, nitrogen...)



Updating staff training and follow-up

- Training for nitrogen alarm management
- ATMPs : declaration of personnel exposed to and monitored by occupational health services



Road safety

- No phone while driving
- List of useful phone numbers
- Reminder of road safety rules
- Car maintenance



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Risk assessment document

Document Unique d'évaluation des risques professionnels		Plusieurs entités sont concernées		Date d'édition:					
Paris Sorbonne Université® - dangers liés PSE									
Nom du Danger	Date et n° de mise à jour	Description du risque	Description de la situation à risque	Mesures de prévention en place	Risque résiduel	Date et n° de l'audit	Date de l'audit	Description	Autorisation
2021 PSE PSE - dangers liés PSE	06/02/2023	Prévention des incendies	Les laboratoires relient soit de la réglementation de leur établissement relatif au premier et au second au travail.	Prévention générale et organisationnelle: Présence sur site (SST) - Carte d'urgence de prévention de sécurité incendie et d'une équipe d'intervention; Contrôle des équipements (détecteur de fumée); Valeur de contrôle de sécurité; Maintenance des installations et équipements; Formation incendie (théorie et pratique); Plan d'évacuation					
				Prévention collective: Contrôle de l'atmosphère; Système d'aération; Système d'alarme; Prévention incendie et fuite					

Regulatory document summarizing

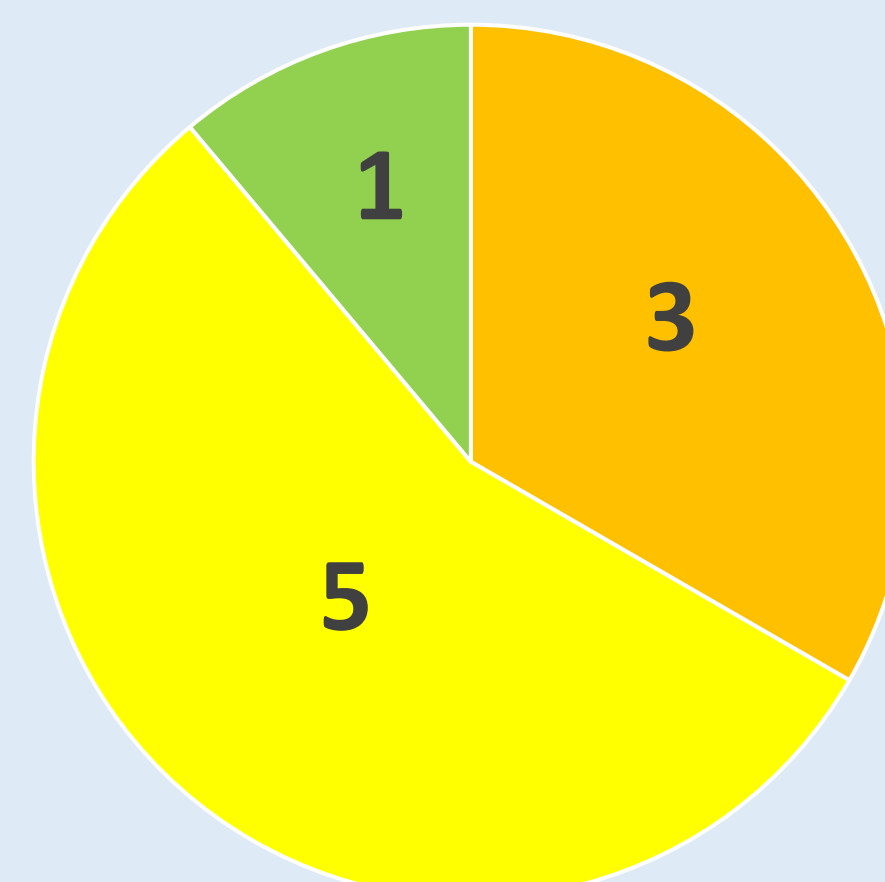
- Description of the situation
- Residual risk
- Action plan

- Risk
- Preventive measures implemented

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Residual risk

Residual risk criticality



■ Significant ■ To be monitored ■ Tolerable

3 risks remain significant related to nitrogen handling :

- Burns
- Explosion
- Hypoxia

Regular training for nitrogen handling and alarm management are needed to mitigate these risks

Discussion and conclusion

In conclusion, the assessment and targeted implementation of preventive measures significantly reduced risk criticality within our unit. This approach enhances staff protection during new assignments and activities. Further evaluations will gauge preventive measure effectiveness in maintaining a safe environment for pharmaceutical personnel involved in cutting-edge clinical research and ATMP management.

