Hospital Pharmacy Central Denmark Region, Production, Aarhus, Denmark

Development of new production when neither packaging nor some of the raw materials conform to European standard

National Poster Prize Winner, Denmark

PC7160

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WHAT WAS DONE?

- A new MR-scanning technology, **hyperpolarization**, enables physicians early detection of treatment effects in e.g. cancer and diabetes.
- A **Pharmacy Kit** is used in the hyperpolarization process and consists of a specially designed packaging containing the contrast agent and buffer solutions.
- The objective was to manufacture Pharmacy Kits complying with **Good Manufacturing Practice** (GMP), **though neither packaging nor two of the raw materials conformed to European standard**.

WHY WAS IT DONE?

A research team at the MR Centre (MRC) wished to set up a production of Pharmacy Kits, but had no prior experience with or license to manufacture drugs. Thus, the hospital pharmacy was asked to participate in the development of such production.

HOW WAS IT DONE?

- A production complying with GMP was developed in **close collaboration with the MRC** and an on going contact with the Danish Medicines Agency.
- The hospital pharmacy executed own **microbiology test** to determine if and for how long the non CE-marked packaging could store the contrast agent and buffer solutions.
- **Risk assessment** of the raw materials not found in the European Pharmacopeia were conducted.
- The method already takes place few other places in and outside Europa. Experiences from these sites were implemented and expanded with **process optimization** and a specially designed equipment for the production.

WHAT HAS BEEN ACHIEVED?

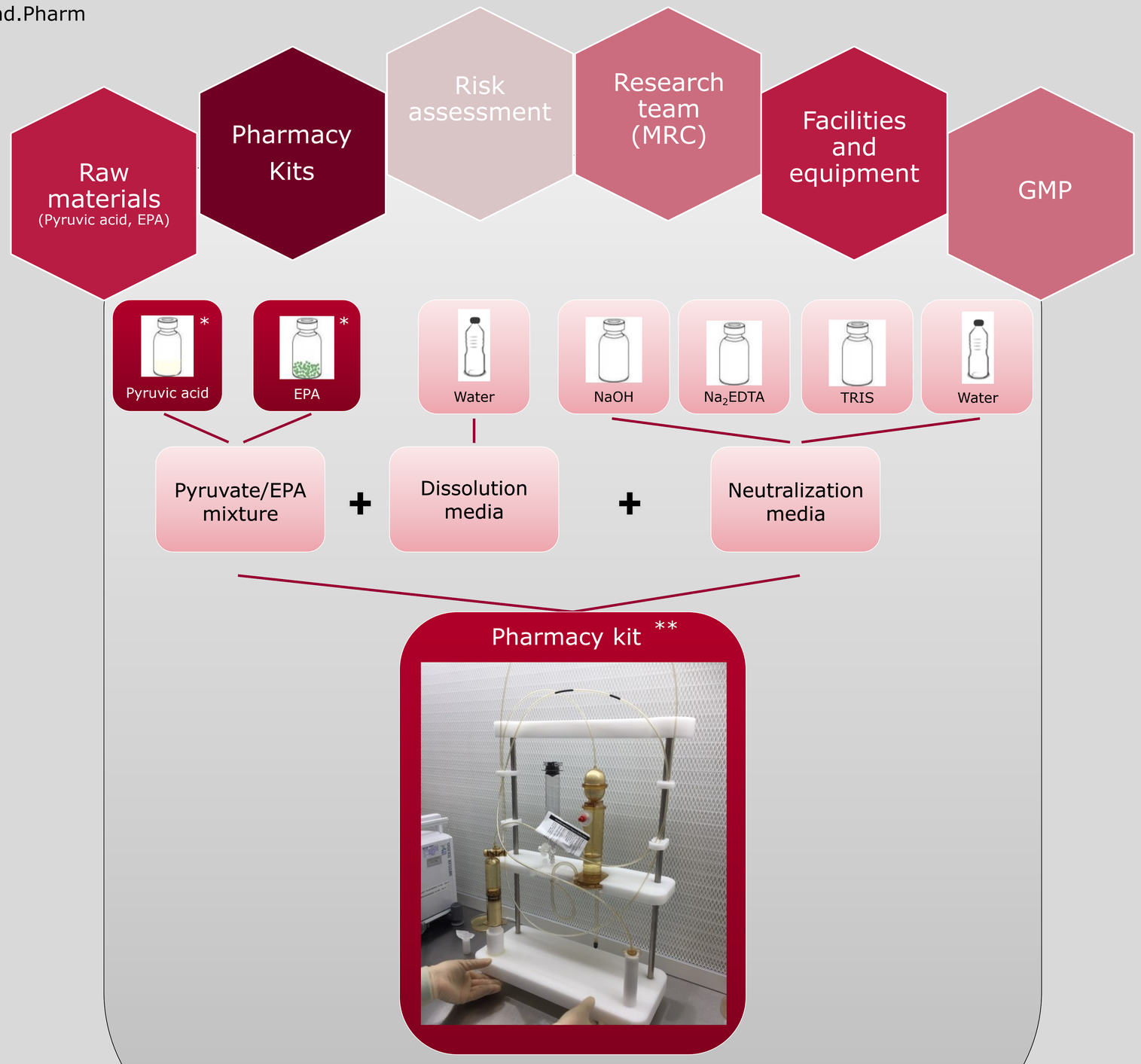
Due to a strong **inter-professional collaboration** between the MRC and the hospital pharmacy and due to qualified risk assessments, it was possible to set up a production of Pharmacy kits according to GMP.

WHAT NEXT?

When researchers contact hospital pharmacies with new ideas we have to be willing to work with GMP in a different way applying knowhow and risk assessments in order to ensure developments within the healthcare systems.

CONCLUSION

THIS PROJECT HAS SHOWN THAT A MUTUALLY DEPENDENT COLLABORATION BETWEEN RESSEARCHERS AND THE HOSPITAL PHARMACY LEADS TO THE MANUFACTURING OF PHARMACY KITS USED IN A NEW DIAGNOSTIC TECHNOLOGY CURRENTLY IN CLINICAL TRIALS IN HUMANS – WITHOUT LOSING FOCUS OF GMP AND PATIENT SAFETY.



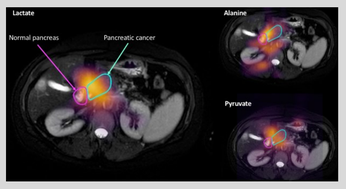
*Raw material not conforming to European standard
**Non sterile and non CE-marked primary packaging

Fig.1: Schematic view of raw materials, solutions and Pharmacy Kit

Biological ^{13}C-enriched substrate is polarized in the Spinlab to provide a very strong MR-signal (Hyperpolarization)

Injection of ^{13}C-hyperpolarized pyruvate

I.V injection of ^{13}C pyruvate allows quantification of break-down products: lactate, alanine and bicarbonate



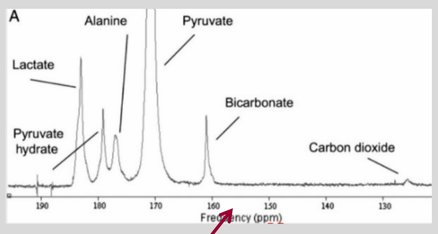


Fig.2: The further processing of Pharmacy Kit before injection the patient

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Acknowledgements:
Prof., DrMedSc. Hans Stødkilde-Jørgensen and his research group at the MR Centre, Aarhus University Hospital, Denmark.