Module-1

History & Introduction:

**Willlian Withering FRS**  (17 March 1741 – 6 October 1799).

He has written a book “An Account of the

Foxglove and Some of its Medicinal Uses: With

Practical Remarks on Dropsy and Other Diseases”.

Explained the events developed after the large doses of foxglove (source of digoxin).

The alarming sign for the regulations of drugs:

Thalidomide disaster.

Thalidomide drug is given for nausea in pregnancy and lead to thousands of children born with deformity limbs (Phocomelia-seal like limbs)

* 1961-Dr. McBride, an Australian doctor, wrote a letter to the editor of the Lancet Journal, in which he suggested a connection between congenital malformation of babies and thalidomide.
* Dr. Lenz - German Pediatrician- Suggested a co-relation of thalidomide and congenital anomalies and published an article.
* Dr. Frances Oldham Kelsey - Pharmacologist and a Physician- The women who struggled hard for thalidomide not to enter into USA market .

The sulfanilamide tragedy:

1937:

* The medicine sulphanilamide was prepared as tablets and capsules from pharmaceutical companies and the S.E. Massengill Company of Bristol, Tennessee, decided that a liquid form of sulphanilamide be prepared with composition of 10 percent sulfanilamide, 72 percent diethylene glycol, and 16 percent water.
* The composition lead to nearly 107 deaths in the USA, because of the use of sulfanilamide elixir, containing diethyl glycol as the solvent.

1938:

* The incident triggered the Food, Drugs and cosmetic act to monitor the safety of new drugs.



1962- USA, Approved an amendment requiring safety and efficacy data of drugs before premarketing submission.

This is called as “Kafauver Haris Amendment”

Informed consent was required & Adverse drug reaction was required to report FDA.

1962: Yellow card Scheme was developed by Bill Inman after Thalidomide disaster.

Adverse reactions are to be reported according to the scheme. It is organized by Medicines and Health care Products Regulatory Agency (MHRA).

Yellow cards are available from pharmacies and a few are in the British National Formulary as tear off pages.

1965: First Pharmaceutical directive 65/65/EC.

European legislation developed . European Law requires all medicinal products to obtain a Marketing Authorisation before they are in the EU market.

**1966- pilot study of Boston Collaborative Drug Surveillance Program started.**

It was the first group to conduct epidemiologic researches to quantify the potential adverse effects of drugs utilizing in-hospital monitoring and had an essential role in the development and application of methods in drug epidemiology.

1968-the WHO Programme for International Drug Monitoring was instituted.

During the 16th World assembly there was a call for “Systematic collection of adverse drug reactions, once the drug is marketed. ten members participated in this program (Australia, UK, USA, Germany, Canada, Ireland, Sweden, Denmark, New Zealand, and Netherlands).

1992- the European Society of Pharmacovigilance (ESoP) was established and changed into the International Society of Pharmacovigilance (IsoP).

ESoP- International non profit scientific organization- it strengths the Pharmacovigilance and enhance for safe and proper use of medicines.

Latet ESoP is changed to ISoP.

1995- the European Medicines Agency (EMA) was set up.

The main aim of EMA is to harmonize the work between the national medicine regulatory bodies.

Over the course of time EMA has developed regulations to Rare diseases, herbal medicines, herbal medicines and advanced therapy medicines.

2001-EudraVigilance came into existence.

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2012- New legislation in European pharmacovigilance (Directive 2010/84/EU).

The pharmacovigilance is further amended in order to strengthen the patient safety and well being.

The Good Pharmacovigilance practices came into existence.

2017- The new EudraVigilance format was launched.

The updated Pharmacovigilance legislation had significant changes in electronic reporting for suspected adverse drug reactions which supports better safety monitoring of drugs and more efficient system for stakeholders.