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The importance of pharmacovigilance

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Safety monitoring of medicinal products:

1. Drug monitoring
2. Pharmaceutical preparations - adverse effects
3. Adverse drug reaction reporting
4. Product surveillance, Postmarketing
5. Legislation, Drug

The purpose of pharmacovigilance:

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Recently, its concerns have been widened to include:

- Herbals
- Traditional and Complementary Medicines
- Blood Products
- Biologicals
- Medical Devices & Vaccines

The specific aims of pharmacovigilance are to:

- Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions,
- Improve public health and safety in relation to the use of medicines
- Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use, and
- Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public
- Pharmacovigilance has developed and will continue to develop in response to the special needs

Biography

Rucha Majmundar Mehta has completed her PhD in Clinical Nutrition from Bombay University and she has completed GCP Auditing studies from BARQA, UK. She is the Director of R Q consultants. She is an Independent GCP auditor (Free Lancer) for 10 years. She developed a Clinical Research Site in a privately owned small sized hospital and heading the site till date. She is providing QA consultation and training to various study sites and QA department of Pharmaceutical Companies. She conducts GCP Sessions during Investigators Meetings globally. She has participated in State, National and International Conferences of Clinical Research as a faculty. She is conducting GCP workshops for Clinical Research Professionals for on-going basis and during conferences. She is active member of EFGCP –AWP and RQA.

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