



Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Government of India



National Conference

Enhancing Pharmaceutical Quality Assurance through Good Manufacturing Practices (GMP) &

Session on Revamped Pharmaceutical Technology Up gradation Assistance Scheme (RPTUAS)

10:30AM onwards

04 **12** **24**

MASSIA's SMT.RATNAPRABHA BALASAHEB PAWAR' Auditorium,
Marathwada Association of Small Scale Industries and Agriculture(MASSIA),
P-25, MIDC Chikalhana, Chh.Sambhajinagar-431006, Behind SBI MIDC Chikalhana Branch

ASSOCIATION PARTNERS



MEDIA PARTNER



Taking this opportunity PHDCCI proposes to organise a conference on Enhancing Pharmaceutical Quality Assurance through Good Manufacturing Practices (GMP) – a crucial initiative aimed at ensuring the consistent production and control of medicinal products to meet the highest quality standards. GMP serves as the cornerstone of pharmaceutical manufacturing, encompassing vital measures to validate, review, and document processes, thereby safeguarding the safety, efficacy, and quality of medicinal products, including vaccines.

Objectives of the conference: ▶▶▶▶

- A** Promoting understanding and implementation of GMP principles among pharmaceutical manufacturers.
- B** Emphasizing the importance of adhering to GMP standards to ensure the safety, efficacy, and quality of medicinal products.
- C** Providing guidance on incorporating GMP requirements into national medicines laws and regulations.
- D** Facilitating the exchange of best practices and experiences related to GMP implementation.

Key Sessions of the Conference: ▶▶▶▶

- Overview of GMP Principles: Comprehensive discussion on quality assurance, process validation, and documentation requirements.
- Legal Components of GMP: Exploration of legal aspects covering responsibilities for distribution, contract manufacturing, testing, and addressing product defects and complaints.
- Annexes to GMP Requirements: Detailed insights into specific GMP requirements for various product classes, such as sterile pharmaceuticals and biological medicinal products.
- WHO Certification Scheme: Understanding the pivotal role of GMP in the WHO Certification Scheme and its significance in ensuring global pharmaceutical product quality.
- Implementation Challenges and Solutions: Identification of common challenges in GMP implementation and strategies for overcoming them.

Expected Outcomes of the Conference: ▶▶▶▶

- Increased awareness and understanding of GMP principles among stakeholders.
- Enhanced compliance with GMP standards for improved quality assurance and patient safety.
- Strengthened regulatory frameworks by incorporating GMP requirements into national medicines laws.
- Establishment of a collaborative network for knowledge sharing among stakeholders.

Over View

- The Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers has launched the Revamped Pharmaceuticals Technology Upgradation Assistance (RPTUAS) Scheme. It is a significant step in government's efforts to help upgrade the technological capabilities of our pharmaceutical industry and ensure its alignment with the global standards.

The approval of the revised Scheme follows a comprehensive review by the Scheme Steering Committee in light of the requirements of the revised Schedule-M of the Drugs and Cosmetics Rule, 1945 as issued by the Department of Health & Family Welfare on 28/12/2023. The revised guideline aims to support the pharmaceutical industry's upgradation to the Revised Schedule-M & WHO-GMP standards, enhancing the quality and safety of pharmaceutical products manufactured in our country.

Key Features of the Revised Scheme:

Broadened Eligibility Criteria: Reflecting a more inclusive approach, eligibility for the PTUAS has been expanded beyond Micro, Small and Medium Enterprises to include any pharmaceutical manufacturing unit with a turnover of less than 500 crores that requires technology and quality upgradation. Preference remains for MSMEs, supporting smaller players in achieving high-quality manufacturing standards.

Flexible Financing Options: The scheme introduces more flexible financing options, emphasizing subsidies on reimbursement basis, over traditional credit-linked approach. This flexibility is designed to diversify the financing options of the participating units, facilitating a more widespread adoption of the scheme.

Comprehensive Support for Compliance with New Standards: In alignment with revised Schedule-M and WHO-GMP standards, the scheme now supports a broader range of technological upgrades. Eligible activities include improvements such as HVAC systems, water and steam utilities, testing laboratories, stability chambers, clean room facilities, effluent treatment, waste management etc. ensuring comprehensive support for participating units.

Objective: To facilitate existing Pharma Units to upgrade to Revised Schedule M and WHO-GMP standards.

Intended: Existing pharmaceutical units having average turnover less than Rs.500 crore

Beneficiaries: over the last 3 years.

INCENTIVE UNDER THE SCHEME

Pharmaceutical units with following average turnover criterion for the last three years will be eligible for incentive subject to a maximum of Rs.1.00 crore as under :-



Turnover from Rs.1.00 crore to less than Rs.50.00 crore – 20% of investment under eligible activities

Turnover from Rs.50.00 crore to less than Rs.250.00 crore – 15% of investment under eligible activities.

Turnover from Rs.250.00 crore to less than Rs.500.00 crore – 10% of investment under eligible activities.



About PHDCCI ◀◀◀◀

PHD Chamber of Commerce and Industry (PHDCCI) has been working as a catalyst for the promotion of Indian industry, trade and entrepreneurship for the past 119 years. It is a forward looking, proactive and dynamic PAN-India apex organization. As a partner in progress with industry and government, PHDCCI works at the grass roots level with strong national and international linkages for propelling progress, harmony and integrated development of the Indian economy.

PHDCCI, acting as the “Voice of Industry & Trade” reaching out to more than 1,50,000 large, medium and small industries, has forged ahead leveraging its legacy with the industry knowledge across multiple sectors to take Indian Economy to the next level.

At the global level, we have been working with the Embassies and High Commissions in India and overseas to bring in the International Best Practices and Business Opportunities.



◀◀◀◀ **For More Detail Please Contact :** ▶▶▶▶

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