MANAGING DIRECTOR, RAAJ GLOBAL PHARMA REGULATORY AFFAIRS CONSULTANTS (GPRAC)

oining the PIC/S forum prove quality standards. It will help boost exports and strengthen India's credentials as amongst the best quality manufacturers of pharmaceuticals globally. It will help pharma companies to facilitate networking and confidencebuilding to promote the quality of inspections and quality assurance of inspectorates, to coordinate training of inspectors. to provide a framework for the exchange of information and experience in GMP, and to enhance global harmonisation of • Harmonised GMP require-GMP

It is going to impact Indian export growth as more and more countries are now looking for PIC/S compliance. India should join the league at the earliest. There is a need to har-

monise GMP inspection standards through the training of inspectors in developing countries to ascertain the quality of starting materials and manufactured pharmaceutical products and the PIC/S provides a platform for activities in this

Original goal

- ▶ PIC/S Goal "To lead the international development, implementation and maintenance of harmonised GMP standards and quality systems if inspectorates in the field of medicinal products".
- ments
- Mutual recognition of inspec-
- Uniform inspection systems
- Training of Inspectors

PIC/S is meant as an instrument to improve co-operation

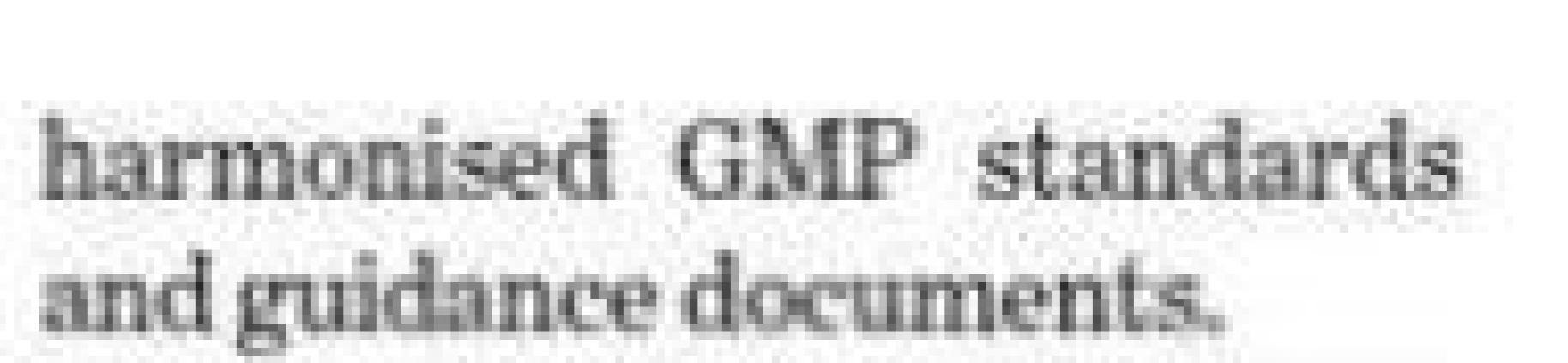
in the field of Good Manufacturing Practices between regumaceutical industry mutual confidence.

The PIC/S has been set up in order to provide, in the interest of public health, for the cooperation between pharma inspectorates with a view to

- fostering and maintaining mutual confidence;
- promoting quality management system for inspectorates and best practices and standards in the field of inspections; and
- contributing to global harmonisation of standards of Assessing (and reassessing) good manufacturing practice (GMP) for medicinal products

Indian regulators should work towards making India a member of PIC/S within the agreed timeframe

Developing and promoting



- Training competent authorities, in particular GMP inspectors.
- GMP Inspectorates.
- Facilitating the co-operation and networking for competent authorities and international organisations.

Benefits of PIC/S Membership

- Accession forced improvements - i.e. discipline
- ▶ Cost saving import control mechanism
- Pacilitated exports of medicines
- Training (seminars, joint inspections, etc.)
- Involvement with developing international GMPs
- ▶ Facilitated MRA with EC
- Networking and personal contacts

