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# Application of Toxicogenomics in Safety Assessment : Regulatory Perspectives

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Toxicogenomics, a rapidly growing field of genomics science, offers the promise for the identification and development of new founded knowledge in toxicology and could play an important role in safety assessment for human health. The use of genomics technologies, particularly gene arrays, as tools for identifying profiles of gene expression associated with particular compounds and toxic responses has shown increasing advantage. If a good correlation exists between gene expression and a toxic mechanism, the genomic data may provide supportive evidence for that mechanism. Developing databases of expression profiles for a wide variety of typical toxic compounds makes it possible to create computational methods that can indicate the toxic potential of a drug or chemical from the pattern of gene expression changes it elicits in *in vitro* or *in vivo* systems. Predictive toxicology and toxicogenomics technologies are of growing interest to government regulatory scientists and major pharmaceutical companies. But, replacing traditional toxicological studies with toxicogenomic approaches as the basis for assessment of toxicity and regulatory decision-making is unlikely in the near future because the genomic approaches have not been scientifically validated. Governmental agencies are currently giving the careful considerations necessary for adequate validation of toxicogenomics-based test methods. It is expected that regulatory authorities will evaluate toxicogenomics data as supplementary information for efficacy and safety alongside classical preclinical and clinical studies for supporting new drug applications.