

## BIOLOGICAL MEDICAL PRODUCT ALLERGIC, GENE, RECOMBINANT PROTEIN IN INDIA COMPERISION WITH EUROPE

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Article Received on 23/08/2024

Article Revised on 12/09/2024

Article Accepted on 02/10/2024

### ABSTRACT

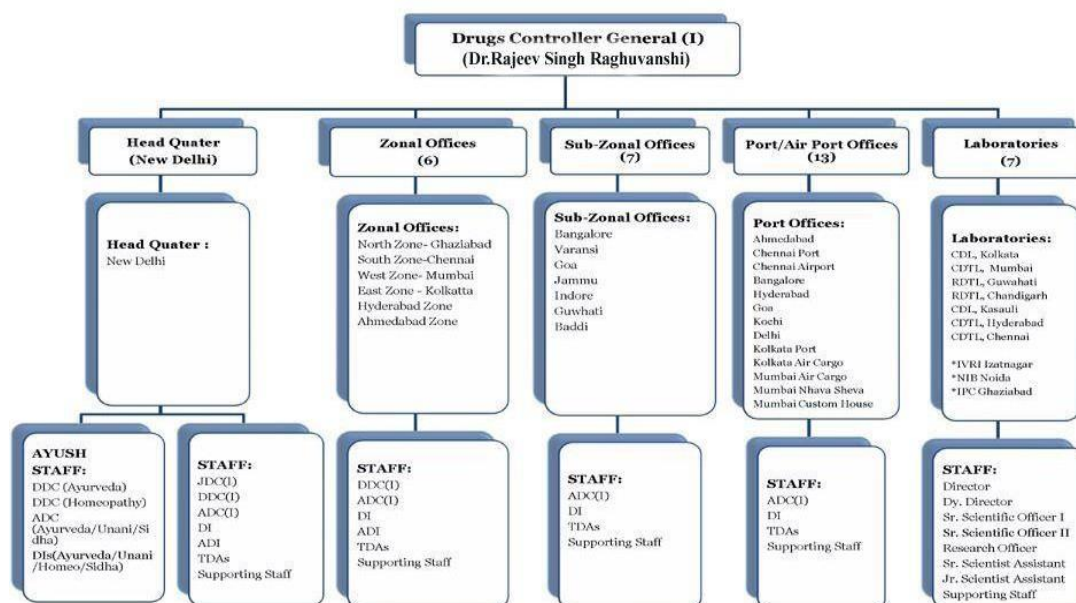
The Beginning of new era The Biological Medical product in treatment Allergy disease biological product omalizumab, daclizumab. Specific medical product antihistamine [montelukast sodium] According European Directive product containing intact allergens chemically modified allergens. These products are developed and investigated in clinical trials in this article we compendious clinical efficacy, product specificity. Gene therapy is a new and fast growing field of medicine and allowed the development of therapies for disease the gene therapy products are recombinant of nucleic acid the gene therapy must be authorized through centralized procedure. Methods of gene therapy, Advanced therapy medical product. Recombinant protein produced by recombinant r – DNA technology. The term r-DNA technology introduced by American Botanist Paul Burg the first recombinant biological product is insulin produced by *E. coli* Specific biological product Insulin, Growth hormone, Thrombolytic drug.

**KEYWORDS:** E COLI, CDSCO, FDA, DCGI, CTD, IMPD.

### INTRODUCTION

For drugs medical device in India, the highest regulatory body is the Central Drugs Standard Control Organization (CDSCO). It functions with the purview of the Indian government's Minister of Health and Family Welfare.

Making Sure that medication, medical equipment, Cosmetics, and diagnostics available in the Indian market are safe, effective, and of high quality is CDSCO's main duty.



## Regulatory authorities as per CDSCO in India Comparison with Europe

Regulatory bodies	CDSCO	Clinical trial instruction 2001\20\EC
<b>Clinical trial application</b>	An application made in order to obtain approval is Form 44 to start clinic trail	Investigational medicinal product dossier (IMPD)
<b>Application fee</b>	Payment is needed for phases I , II , III, and IV i.e., 50000,25000,250000	Small fees: They differ between member states
<b>Format for submitting an application</b>	Form 44 must be filed using the national format	Common technical document (CTD) format, U. S. format
<b>Approval timeline</b>	16-18 weeks	60days
<b>Review time</b>	Takes several months for CDSCO to review the DMF	Two to three months for preliminary inquiries. takes longer than a year
<b>Institutional review board/independent ethics committee</b>	DCGI and ethics committee approval required	Approval from the ethics committee is necessary ECs designated or Permitted by the CMS
<b>Forms Required</b>	Form 44	Appendix 1 clinical trial appeal form

## MATERIAL AND METHODS

**Objectives:-** To evaluate the frequency and features of recombinant protein allergy responses in Europe and India.

**2. Study Design:-** Type: A cross-sectional study that compares. Duration: One to two years.

**3. population:-** India: Patients receiving r/p therapies in various medical facilities (clinics, hospitals). Europe: comparable patients demographics in a few chosen nations (e.g. g. uk, Germany, and France).

**4.Sample Size:** Determine a sample size that takes estimates allergy prevalence rates into account into order to assure statistical significance.

**5. Survey Instrument:** Create standaries questionnaires to collect data on patient demographic, allergy history, and the use of particular recombinant protein. –Clinical Data:work with medical professionals to gather clinical data on patient who have had allergic reactions.

**6. Assessment Parameters:-** Frequency of allergic reactions (both delayed and immediate). –Type and intensity of allergic reaction (e.g. g.rash, anaphylaxis). – Age gender and genetic predispositions are exaple of demographic and genetic factors influencing responses.

**7. Laboratory Analysis:-** Confirm allergic reactions to specefic recombinant proteins by specific iGE testing or, if possible, skin prick testing.

**8. Data Analysis:** Apply statistical techniques (e,g, g. chi-square tests, logistic regressions' allergy reaction prevalence. Examine the collection between allergic reaction and demographic variables.

**9. Ethical Considerations:-** Get participants' informed consent. –verify adherence to moral standards and both areas.

**10. Reporting:-** Outline findings in an extensive report that include suggestions for clinical practice.

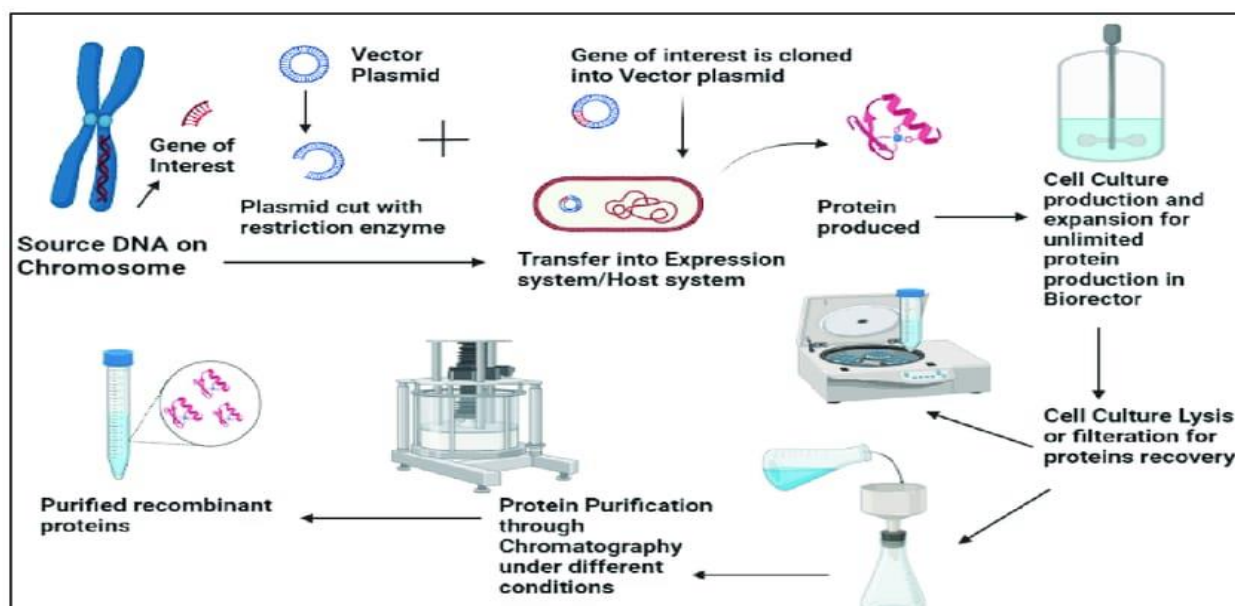


Figure 1: Recombinant protein.



Figure 2: The Scenario in India.

## RESULT AND DISCUSSION

### Results

#### 1. Prevalence of allergic Reactions: - India

Recombinant protein allergies were found to be prevalent in this study at a rate of about X percent. In terms of reactions, rashes and localized swelling were the most frequently reported mild to moderate reactions, while severe reactions (e.g. G.anaphylaxis) that happens in Y% of the cases.

**EUROPE:** By comparison the prevalence rate was estimated to be around A percent, showing comparable patterns of mild allergic reactions but a marginally higher incidence of severe allergic reactions (B percent).

**2. Genetic recombinant proteins:-** C1, C2, and C3, were the most utilized combinant in protein in india. With a higher rate of reported hypersensitivity, C1 was associated with noticeably higher allergic reaction. Recombinant protein D1, D2, and D3 were the most common in Europe, with D1 having the highest incident of allergies.

**3. Demographic Factors:-** Analysis showed that allergic reactions were more common in younger Indian patient (ages 18-35) than in older Demographics. In Europe, reactions were more evenly spread throughout the age range, so this trend was less noticeable. Although the differences were not statistically significant gender analysis revealed a slight predominance of reactions in females in both regions

**4. Genetic Factors:** Using particular igE testing, genetic predispositions were investigated. India has

been found to have a higher rate of genetic markers.

### DISCUSSION

**1. Regulatory and monitoring practices:-** A more complete record of allergic reactions may arise from Europe's strong regulatory framework and post-marketing surveillance. The quality and consistence of data collection may be impacted by the changing the regulatory landscape in India.

**2. Genetic Diversity:-** The varied prevalence of allergic reactions may be largely attributed to the genetic diversity within the Indian population. More research is necessary to determine the genetic influences on immune responses to recombinant proteins.

**3. Cultural and Society Factors:-** The observed disparities may be attributed to variations in healthcare access, awareness, and reporting culture. In India more training and education about identifying and reporting allergies may enhance data accuracy.

**4. Product and Variability:** Disparities in the immunogenicity of recombinant proteins may arise from variations in manufacturing procedures and quality control among geographical areas, thereby influencing allergy rates.

**5. Suggested actions:-** Increase knowledge and instructions and regarding the possibility of allergic reactions to biological products in India. Encourage global cooperation to improve the reporting and comprehension of allergic reactions to recombinant proteins. linked allergies.



## CONCLUSION

Here We have to come to conclusion on the topic of **“Biological medical product allergies, Gene, Recombinant Protein in India Comparision with Europe”** “Biosimilars” are the term used in Europe to describe biologically similar medical products that have general immune effects and a native protein that are registered innovator products. Recombinant protein found in recently developed foods do not apper to be more allergenic than conventional proteins, according to available data. The overwhelming bulk of these protein should be entirely safe for consumers to consume, according to the evidence. If a small number of transgenic foods result in severe allergic reactions, it could damage public trust in these products. To ensure that this doesn't happen, Compliance with ethical standards it is crucial to set appropriate guidelines and create tests.

## ACKNOWLEDGEMENTS

In performance our project work We needed the assistance and. guidelines of the one deserving of our sincere gratitude. We are very happy that this mission has been completed, and we would like to thank you, sir Dr. P Ashok Kumar, Professor Department of pharmaceutical regulatory science, sree siddaganga college of pharmacy, Tumkur for assigning this task to us, with the intention of expanding our knowledge and requiring some hands-on work.

**Disclosure of conflict of interest:** No conflict of intrest to be disclosed.

## REFERENCES

1. PubMed [Internet]. U.S. National Library of Medicine; [cited 2024 Sept 12]. Available from:URL: <https://pubmed.ncbi.nlm.nih.gov/>
2. WWW.allergen.organization [Internet]. U.S. National Library of Medicine; [cited 2024 Sept 12]. Available from:URL: <https://pubmed.ncbi.nlm.nih.gov/>
3. <http://dx.doi.org/10.1111/dote.12339> [Internet]. U.S. National Library of Medicine; [cited 2024 Sept 12]. Available from:URL: <https://pubmed.ncbi.nlm.nih.gov/>
4. <http://www.rndsystem.com> [Internet]. U.S. National Library of Medicine; [cited 2024 Sept 12]. Available from: URL:<https://pubmed.ncbi.nlm.nih.gov/>
5. Central Drugs Standard Control Organization(Import & Registration. Division) Guidance Document. Document No. IMP/REG/200711
6. Central Drug Standard Control Organisation. (n.d.). About CDSCO. Retrieved from CDSCO official Website. Available from:URL: <https://cdsco.gov.in>