

**Activity Outline**  
**FDA Grand Rounds: Immune system responses to therapeutic proteins: Getting up close and personal**  
**September 9, 2021**  
**Virtual: Adobe platform**

**Activity Coordinator:**

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**Series Description**

The FDA Grand Rounds is webcast every other month to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

**Lecture Description**

Proteins used as therapeutics have become an essential part of modern medicine. Immunogenicity (anti-drug antibodies that target the protein-therapeutic) is a significant impediment to development and licensure of any therapeutic-protein. The lecture will illustrate how judicious application of tools available for immunogenicity risk-assessment can permit better decision-making during drug-development, licensure, and clinical-trials.

**References**

- Z.E. Sauna, D. Lagassé, J. Pedras-Vasconcelos, B. Golding & A.S. Rosenberg. Evaluating and mitigating the immunogenicity of therapeutic proteins. Trends Biotechnol 36: 1068-1084, 2018
- V.L. Simhadri, J. McGill, S. McMahon, J. Wang, H. Jian & Z.E. Sauna. Prevalence of Pre-existing Antibodies to CRISPR-associated Nuclease Cas9 in the US Population. Mol Ther Methods Clin Dev. 10: 105-112, 2018
- K. Lamberth, S. Louise Reedtz-Runge, J. Simon, K. Klementyeva, G.S. Pandey, S.B. Padkjær, V. Pascal, I.R. León, C.N. Gudme, S. Buus & Z.E. Sauna. Post-hoc assessment of the immunogenicity of bioengineered Factor VIIa demonstrates utility of preclinical tools. Sci. Transl. Med. 9: eaag1286, 2017

**Series Objectives**

- Discuss the research conducted at the FDA
- Explain how FDA science impacts public health

**Learning Objectives** After completion of this activity, the participant will be able to:

- Identify the economic and personal costs of immunogenicity to protein therapeutics
- Explain the use of non-clinical immunogenicity assays for determining immunogenicity risk
- List some in silico, in vitro and ex vivo methods used to evaluate immunogenicity of therapeutic proteins

**Target Audience**

This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

**Agenda**

**Lecture 1 September 9, 2021**

Time	Topic	Speaker
12:00 - 1:00 PM	Immune system responses to therapeutic proteins: Getting up close and personal	Zuben Sauna, Ph.D.

**Continuing Education Accreditation**



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INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.



This activity was planned by and for the healthcare team, and learners will receive 1 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

## **CME**

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

## **CPE**

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-21-016-L04-P for 1.00 contact hour(s).

## **CNE**

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

## **Requirements for Receiving CE Credit**

**Physicians, pharmacists, nurses, and those claiming non-physician CME:** participants must attest to their attendance and complete the final activity evaluation via the CE Portal ([ceportal.fda.gov](http://ceportal.fda.gov)). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

## **Important Note regarding completion of evaluations and receiving credit**

Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit. Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 8 weeks after the last session of the activity to obtain their CE credit.

## **Disclosure**

### **Faculty**

- Sauna, Zuben, Ph.D., Research Biologist, Center for Biologics Evaluation and Research *nothing to disclose*

### **Planning Committee**

- Dinatale, Miriam, Team Leader, Food and Drug Administration *nothing to disclose*
- Pfundt, Tiffany, PharmD, Pharmacist, FDA *nothing to disclose*
- Wheelock, Leslie, RN, MS, Director, OSPD, FDA, OC, OCS, OSPD *nothing to disclose*

### **CE Consultation and Accreditation Team**

- Bryant, Traci, M.A.T., CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

## **Registration Fee and Refunds**

Registration is complimentary, therefore refunds are not applicable.