

# Meenu Wadhwa

## List of Publications by Year in descending order

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89  
papers

2,719  
citations

236912  
25  
h-index

189881  
50  
g-index

90  
all docs

90  
docs citations

90  
times ranked

3079  
citing authors

| #  | ARTICLE  | IF   | CITATIONS |
|----|--|------|-----------|
| 1  | Protein Engineering and HDX Identify Structural Regions of G-CSF Critical to Its Stability and Aggregation. Molecular Pharmaceutics, 2022, 19, 616-629.  | 4.6  | 4         |
| 2  | WHO informal consultation on revision of guidelines on evaluation of similar biotherapeutic products, virtual meeting, 30 June – 2 July 2021. Biologicals, 2022, 76, 1-9.  | 1.4  | 2         |
| 3  | 2021 White Paper on Recent Issues in Bioanalysis: ISR for Biomarkers, Liquid Biopsies, Spectral Cytometry, Inhalation/Oral & Multispecific Biotherapeutics, Accuracy/LLOQ for Flow Cytometry (<u>Part 2</u> – Recommendations on Biomarkers/CDx Assays Development & Validation,) Tj ETQq1 1 0.784314 rgBTq/Overlock                   | 1.5  | 14        |
| 4  | 2021 White Paper on Recent Issues in Bioanalysis: Mass Spec of Proteins, Extracellular Vesicles, CRISPR, Chiral Assays, Oligos; Nanomedicines Bioanalysis; ICH M10 Section 7.1; Non-Liquid & Rare Matrices; Regulatory Inputs (<u>Part 1A</u> – Recommendations on Endogenous Compounds, Small Molecules,) Tj ETQq0 0 0 rgBTq/Overlock | 1.5  | 14        |
| 5  | 2021 White Paper on Recent Issues in Bioanalysis: TAB/INAb, Viral Vector CDx, Shedding Assays; CRISPR/Cas9 & CAR-T Immunogenicity; PCR & Vaccine Assay Performance; ADA Assay Comparability & Cut Point Appropriateness (<u>Part 3</u> – Recommendations on Gene Therapy,) Tj ETQq1.1 0.784314 rgBTq/Overlock                          | 1.5  | 14        |
| 6  | Regulatory challenges with biosimilars: an update from 20 countries. Annals of the New York Academy of Sciences, 2021, 1491, 42-59.  | 3.8  | 20        |
| 7  | Maintaining “standards”™ for biosimilar monoclonal antibodies. Nature Biotechnology, 2021, 39, 276-280.  | 17.5 | 12        |
| 8  | The First WHO International Standard for Adalimumab: Dual Role in Bioactivity and Therapeutic Drug Monitoring. Frontiers in Immunology, 2021, 12, 636420.  | 4.8  | 7         |
| 9  | Therapeutic use of specific tumour necrosis factor inhibitors in inflammatory diseases including COVID-19. Biomedicine and Pharmacotherapy, 2021, 140, 111785.   | 5.6  | 14        |
| 10 | The First WHO International Standard for Harmonizing the Biological Activity of Bevacizumab. Biomolecules, 2021, 11, 1610.   | 4.0  | 2         |
| 11 | WHO International Standards and Reference Preparations for Cytokines and Growth Factors. Journal of Leukocyte Biology, 2020, 107, 159-160.   | 3.3  | 0         |
| 12 | Recommendations for the Development and Validation of Immunogenicity Assays in Support of Biosimilar Programs. AAPS Journal, 2020, 22, 7.  | 4.4  | 17        |
| 13 | WHO implementation workshop on guidelines on procedures and data requirements for changes to approved biotherapeutic products, Seoul, Republic of Korea, 25–26 June 2019. Biologicals, 2020, 65, 50-59.  | 1.4  | 1         |
| 14 | The regulatory landscape of biosimilars: WHO efforts and progress made from 2009 to 2019. Biologicals, 2020, 65, 1-9.  | 1.4  | 34        |
| 15 | Harmonization and standardization of immunogenicity assessment of biotherapeutic products. Bioanalysis, 2019, 11, 1593-1604.   | 1.5  | 8         |
| 16 | Bioanalytical strategies in determining immunogenicity. Bioanalysis, 2019, 11, 1535-1537.  | 1.5  | 0         |
| 17 | The impact of thioredoxin reduction of allosteric disulfide bonds on the therapeutic potential of monoclonal antibodies. Journal of Biological Chemistry, 2019, 294, 19616-19634.  | 3.4  | 10        |
| 18 | The first World Health Organization International Standard for infliximab products: A step towards maintaining harmonized biological activity. MABs, 2019, 11, 13-25.  | 5.2  | 16        |

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|----|---|-----|-----------|
| 19 | Endothelial cell functions impaired by interferon in vitro: Insights into the molecular mechanism of thrombotic microangiopathy associated with interferon therapy. <i>Thrombosis Research</i> , 2018, 163, 105-116.                                      | 1.7 | 41        |
| 20 | WHO informal consultation on development of guidelines on procedures and data requirements for changes to approved biotherapeutic products, Seoul, Republic of Korea, 27-28 April 2017. <i>Biologicals</i> , 2018, 52, 83-91.                             | 1.4 | 2         |
| 21 | 2018 White Paper on Recent Issues in Bioanalysis: focus on immunogenicity assays by hybrid LBA/LCMS and regulatory feedback (Part 2 - PK, PD & ADA assays by hybrid LBA/LCMS & regulatory) <i>Trends in Biotechnology</i> , 2018, 38, 101-114.            | 1.7 | 14        |
| 22 | 2018 White Paper on Recent Issues in Bioanalysis: focus on flow cytometry, gene therapy, cut points and key clarifications on BAV (Part 3 - LBA/cell-based assays: immunogenicity, biomarkers and PK) <i>Trends in Biotechnology</i> , 2018, 38, 115-122. | 1.7 | 10        |
| 23 | Anti-therapeutic antibodies and their clinical impact in patients treated with the TNF antagonist adalimumab. <i>Cytokine</i> , 2017, 96, 16-23.  | 3.2 | 24        |
| 24 | Surrogate CD16-expressing effector cell lines for determining the bioactivity of therapeutic monoclonal antibodies. <i>Journal of Pharmaceutical and Biomedical Analysis</i> , 2017, 143, 188-198.  | 2.8 | 6         |
| 25 | Establishment of the first WHO International Standard for etanercept, a TNF receptor II Fc fusion protein: Report of an international collaborative study. <i>Journal of Immunological Methods</i> , 2017, 447, 14-22.                                    | 1.4 | 11        |
| 26 | Influence of <i>Escherichia coli</i> chaperone DnaK on protein immunogenicity. <i>Immunology</i> , 2017, 150, 343-355.  | 4.4 | 18        |
| 27 | IL-27 Promotes Proliferation of Human Leukemic Cell Lines Through the MAPK/ERK Signaling Pathway and Suppresses Sensitivity to Chemotherapeutic Drugs. <i>Journal of Interferon and Cytokine Research</i> , 2016, 36, 302-316.                            | 1.2 | 25        |
| 28 | Editor's Highlight: Subvisible Aggregates of Immunogenic Proteins Promote a Th1-Type Response. <i>Toxicological Sciences</i> , 2016, 153, 258-270.  | 3.1 | 33        |
| 29 | Establishment of the first WHO Erythropoietin antibody reference panel: Report of an international collaborative study. <i>Journal of Immunological Methods</i> , 2016, 435, 32-42.   | 1.4 | 9         |
| 30 | Quality and Batch-to-Batch Consistency of Original and Biosimilar Epoetin Products. <i>Journal of Pharmaceutical Sciences</i> , 2016, 105, 542-550.   | 3.3 | 18        |
| 31 | Establishment of the first international standard for PEGylated granulocyte colony stimulating factor (PEG-G-CSF): Report of an international collaborative study. <i>Journal of Immunological Methods</i> , 2015, 416, 17-28.                            | 1.4 | 12        |
| 32 | Immunogenicity assessment of biotherapeutic products: An overview of assays and their utility. <i>Biologicals</i> , 2015, 43, 298-306.  | 1.4 | 114       |
| 33 | Access to safe and effective biopharmaceuticals. <i>GaBI Journal</i> , 2015, 4, 108-109.  | 0.3 | 1         |
| 34 | Standardization of Human IL-29 (IFN- $\gamma$ ): Establishment of a World Health Organization International Reference Reagent for IL-29 (IFN- $\gamma$ ). <i>Journal of Interferon and Cytokine Research</i> , 2014, 34, 876-884.                         | 1.2 | 5         |
| 35 | Detection of anti-cytokine antibodies and their clinical relevance. <i>Expert Review of Clinical Immunology</i> , 2014, 10, 1029-1047.  | 3.0 | 17        |
| 36 | Biosimilar monoclonal antibodies approved for use in the EU. <i>GaBI Journal</i> , 2014, 3, 9-10.   | 0.3 | 2         |

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|----|--|------|-----------|
| 37 | Use of a Standardized MxA Protein Measurement-Based Assay for Validation of Assays for the Assessment of Neutralizing Antibodies Against Interferon- $\beta$ . Journal of Interferon and Cytokine Research, 2013, 33, 660-671. | 1.2  | 17        |
| 38 | Severity of the TGN1412 trial disaster cytokine storm correlated with IL-2 release. British Journal of Clinical Pharmacology, 2013, 76, 299-315.   | 2.4  | 56        |
| 39 | The 2nd International standard for Interleukin-2 (IL-2) Report of a collaborative study. Journal of Immunological Methods, 2013, 397, 1-7.   | 1.4  | 3         |
| 40 | Immunoglobulin G1 and immunoglobulin G4 antibodies in multiple sclerosis patients treated with IFN $\beta$ interact with the endogenous cytokine and activate complement. Clinical Immunology, 2013, 148, 177-185.             | 3.2  | 17        |
| 41 | European perspective on biosimilars. Bioanalysis, 2013, 5, 521-524.  | 1.5  | 6         |
| 42 | Development and characterization of a non-cell-based assay to assess the presence of neutralizing antibodies to interferon-beta in clinical samples. Journal of Immunological Methods, 2013, 395, 37-44.                       | 1.4  | 15        |
| 43 | Detection of neutralizing antibodies to erythropoietin by inhibition of rHuEPO-stimulated EGR1 gene expression in the UT-7/EPO cell line. Journal of Immunological Methods, 2013, 387, 191-198.                                | 1.4  | 3         |
| 44 | Biosimilars: what clinicians should know. Blood, 2012, 120, 5111-5117.   | 1.4  | 314       |
| 45 | The 1st International standard for transforming growth factor- $\beta$ 3 (TGF- $\beta$ 3). Journal of Immunological Methods, 2012, 380, 1-9.   | 1.4  | 1         |
| 46 | Freeze drying formulation using microscale and design of experiment approaches: a case study using granulocyte colony-stimulating factor. Biotechnology Letters, 2012, 34, 641-648.  | 2.2  | 14        |
| 47 | An Assessment of Biological Potency and Molecular Characteristics of Different Innovator and Noninnovator Interferon-Beta Products. Journal of Interferon and Cytokine Research, 2011, 31, 383-392.                            | 1.2  | 26        |
| 48 | Endothelial cells co-stimulate peripheral blood mononuclear cell responses to monoclonal antibody TGN1412 in culture. Cytokine, 2011, 55, 141-151.   | 3.2  | 23        |
| 49 | Biosimilars—why terminology matters. Nature Biotechnology, 2011, 29, 690-693.  | 17.5 | 174       |
| 50 | The 2nd International Standard for human granulocyte colony stimulating factor. Journal of Immunological Methods, 2011, 367, 63-69.  | 1.4  | 6         |
| 51 | Comparison of novel methods for predicting the risk of pro-inflammatory clinical infusion reactions during monoclonal antibody therapy. Journal of Immunological Methods, 2011, 371, 134-142.                                  | 1.4  | 27        |
| 52 | Intended use of Reference Products & WHO International Standards/Reference Reagents in the development of Similar Biological Products (Biosimilars). Biologicals, 2011, 39, 262-265.   | 1.4  | 17        |
| 53 | WHO/KFDA joint workshop on implementing WHO guidelines on evaluating similar biotherapeutic products, Seoul, Republic of Korea 24–26 August, 2010. Biologicals, 2011, 39, 349-357.   | 1.4  | 11        |
| 54 | Evaluation of similar biotherapeutic products: Scientific and regulatory challenges. Biologicals, 2011, 39, 249.   | 1.4  | 1         |

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|----|--|-----|-----------|
| 55 | Treatment of colitis with a commensal gut bacterium engineered to secrete human $\text{tgf-}\beta 1$ under the control of dietary xylan. <i>Inflammatory Bowel Diseases</i> , 2011, 17, 1925-1935.   | 1.9 | 83        |
| 56 | Are neutralizing anti-“GM-CSF autoantibodies present in all healthy persons?. <i>Blood</i> , 2010, 115, 433-434.   | 1.4 | 11        |
| 57 | WHO international cytokine standards and reference preparations. <i>Journal of Leukocyte Biology</i> , 2010, 88, 425-426.  | 3.3 | 1         |
| 58 | Unwanted immunogenicity: lessons learned and future challenges. <i>Bioanalysis</i> , 2010, 2, 1073-1084.   | 1.5 | 27        |
| 59 | Detection of neutralizing interleukin-17 antibodies in autoimmune polyendocrinopathy syndrome-1 (APS-1) patients using a novel non-cell based electrochemiluminescence assay. <i>Cytokine</i> , 2010, 50, 129-137.   | 3.2 | 14        |
| 60 | World Health Organization International Cytokine Standards and Reference Preparations. <i>Journal of Interferon and Cytokine Research</i> , 2010, 30, 639-641.   | 1.2 | 1         |
| 61 | A novel bioassay for B-cell activating factor (BAFF) based on expression of a BAFF-receptor ectodomain-tumour necrosis factor-related apoptosis-inducing ligand (TRAIL) receptor-2 endodomain fusion receptor in human rhabdomyosarcoma cells. <i>Journal of Immunological Methods</i> , 2008, 337, 63-70. | 1.4 | 6         |
| 62 | Haematopoietic growth factors and their therapeutic use. <i>Thrombosis and Haemostasis</i> , 2008, 99, 863-873.  | 3.4 | 40        |
| 63 | Assessment of Unwanted Immunogenicity. , 2008, , 57-73.  |     | 4         |
| 64 | Haematopoietic growth factors and their therapeutic use. <i>Thrombosis and Haemostasis</i> , 2008, 99, 863-73.   | 3.4 | 15        |
| 65 | “Cytokine Storm” in the Phase I Trial of Monoclonal Antibody TGN1412: Better Understanding the Causes to Improve PreClinical Testing of Immunotherapeutics. <i>Journal of Immunology</i> , 2007, 179, 3325-3331.   | 0.8 | 311       |
| 66 | Unwanted Immunogenicity: Implications for Follow-on Biologicals. <i>Drug Information Journal</i> , 2007, 41, 1-9.  | 0.5 | 10        |
| 67 | Continuous delivery of human type I interferons ( $\beta 1/\beta 2$ ) has significant activity against acute myeloid leukemia cells in vitro and in a xenograft model. <i>Blood</i> , 2007, 109, 1244-1247.  | 1.4 | 27        |
| 68 | Strategies and Assays for the Assessment of Unwanted Immunogenicity. <i>Journal of Immunotoxicology</i> , 2006, 3, 115-121.  | 1.7 | 28        |
| 69 | Biological activity of interleukins-28 and -29: Comparison with type I interferons. <i>Cytokine</i> , 2005, 31, 109-118.   | 3.2 | 202       |
| 70 | Problems in early diagnosis of bladder cancer in a spinal cord injury patient: Report of a case of simultaneous production of granulocyte colony stimulating factor and parathyroid hormone-related protein by squamous cell carcinoma of urinary bladder. <i>BMC Urology</i> , 2002, 2, 8.                | 1.4 | 27        |
| 71 | Cytokine levels as performance indicators for white blood cell reduction of platelet concentrates. <i>Vox Sanguinis</i> , 2002, 83, 125-136.   | 1.5 | 32        |
| 72 | Chemokine/Chemokine Receptor Nomenclature. <i>Journal of Interferon and Cytokine Research</i> , 2002, 22, 1067-1068.   | 1.2 | 273       |

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|----|---|------|-----------|
| 73 | Autologous plasma activates Akt/protein kinase B and enhances basal survival and resistance to DNA damage-induced apoptosis in B-chronic lymphocytic leukaemia cells. British Journal of Haematology, 2001, 114, 608-615. | 2.5  | 30        |
| 74 | Cytokines in WBC-reduced apheresis PCs during storage: a comparison of two WBC-reduction methods. Transfusion, 2000, 40, 1118-1126.   | 1.6  | 46        |
| 75 | Sustained Expression of CD154 (CD40L) and Proinflammatory Cytokine Production by Alloantigen-Stimulated Umbilical Cord Blood T Cells. Journal of Immunology, 2000, 164, 6206-6212.  | 0.8  | 41        |
| 76 | Are cytokines in platelet concentrates responsible for febrile transfusion reactions?. Transfusion Science, 1997, 18, 367-371.  | 0.6  | 5         |
| 77 | Cytokine Contamination of Biological Products. Biologicals, 1997, 25, 307-318.  | 1.4  | 0         |
| 78 | IL-4 and TNF- $\alpha$ -MEDIATED PROLIFERATION OF THE HUMAN MEGAKARYOCYTIC LINE M-07E IS REGULATED BY INDUCED AUTOCRINE PRODUCTION OF GM-CSF. Cytokine, 1996, 8, 900-909.   | 3.2  | 7         |
| 79 | Neutralising antibodies to granulocyte-macrophage colony stimulating factor (GM-CSF) in carcinoma patients following GM-CSF combination therapy. Medical Oncology, 1996, 13, 161-166.                                     | 2.5  | 15        |
| 80 | Transforming growth factor- $\beta$ 1 blocks interleukin 4 induced cell proliferation by inhibiting a protein tyrosine phosphatase essential for signal transduction. Cytokine, 1994, 6, 389-398.                         | 3.2  | 9         |
| 81 | A novel, sensitive bioassay for transforming growth factor $\beta$ 2. Journal of Immunological Methods, 1993, 164, 61-67.   | 1.4  | 32        |
| 82 | Mechanisms of inhibition of T cell IL-2 secretion by factor VIII concentrates. British Journal of Haematology, 1992, 82, 575-583.   | 2.5  | 24        |
| 83 | Development of immunoassays for human interleukin 3 and interleukin 4, some of which discriminate between different recombinant DNA-derived molecules. Cytokine, 1991, 3, 562-567.  | 3.2  | 21        |
| 84 | Reconstitution of interleukin 2 with albumin for infusion. Lancet, The, 1990, 335, 1602-1603.   | 13.7 | 8         |
| 85 | Production of polyclonal and monoclonal antibodies to human granulocyte colony-stimulating factor (GCSF) and development of immunoassays. Journal of Immunological Methods, 1990, 128, 211-217.                           | 1.4  | 7         |
| 86 | DEMONSTRATION OF CYTOKINES IN BIOLOGICAL MEDICINES PRODUCED IN MAMMALIAN CELL LINES. Lancet, The, 1989, 334, 1011-1012.   | 13.7 | 5         |
| 87 | In vivo administration of interleukin 2 stimulates mitosis in thymus and bone marrow. European Journal of Immunology, 1986, 16, 1171-1174.  | 2.9  | 8         |
| 88 | Interleukin 2 stimulates T cell proliferation using a calcium flux. Immunology Letters, 1985, 10, 297-302.  | 2.5  | 23        |
| 89 | Impact of Formulation Choices on the Freeze-Drying of an Interleukin-6 Reference Material. Frontiers in Molecular Biosciences, 0, 9, .  | 3.5  | 1         |