

- 2020
 - JPM 2018
 - 2018 DC
 - 2018
 - 2018
 - 2019
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 - 2017
 - 2017
 - 2018

(Professional Working Experiences):

1983 07 -1985 11 :
 1985 11 -1988 05 :
 1988 05 -1989 05 :
 1989 05 -1991 12 : MD
 1991 12 -1992 11 :
 1992 11 -1995 04 :
 1995 04 -1996 10 :
 1996 10 -1998 07 : GeneNetwork

 1998 07 -1999 07 : ()A
 1999 07 -2002 07 : A
 2002 07 -2004 11 : (CDER),
 GS-15-10
 2004 11 -2008 06 : (CBER),
 GS-15-10
 2008 06 -2017 12 : (CBER),
 GS-15-10
 2017 12 -2018 12
 2018 05 -2019 12 CEO
 2019 05 -2021 05
 2021 05 -
 2020 04 -
 2018 06 -

(Briefing Summary):

- FDA (Previous Working Experiences):

A (FDA)
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2002 FDA GS-
15/10 FDA CDER
Pre-IND/IND/NDA FDA
Guidance for Industry

2004 FDA CBER
Pre-IND/IND/IDE/501K
BLA/PMA/NDA

Guidance for Industry EMEA
Biological Regulatory Science Communications

FDA

Alzheimer disease

FDA

Work104BB22C1511 Tm0 BT/F2 11.04 Tf1 0 0 1 72.024 530.11 Tm0 g0 G0D5835BE0D2D150.0000091

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 - CFDA ;
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 - FDA
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 - FDA /
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 - CFDA (CDE)
 - FDA
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 - (Clinical Working Experiences):
 A A A A AN A A c A
 A Medical College of Wisconsin, Milwaukee, Wisconsin A
 A Medical Training System, Providence Hospital, Southfield, Michigan)A
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(Education Background):

1978 11 -1983 07 (BS-China Medical University, Shenyang,
 Liaoning, P.R. China)
 1984 06 -1986 07
 (MPH-Johns Hopkins University and Beijing Medical University,
 Beijing, P.R. China)
 1998 07 -1999 07 : (Medical Training
 System, Providence Hospital, Southfield, Michigan)A
 1999 07 -2002 07 (MD Certificate-Medical
 College of Wisconsin, Milwaukee, Wisconsin)A
 1992 11 -1995 04 : A

(Certificates):

/ ECFMG Certificate 1998
 Preliminary Surgery Certificate 1999
 ACLS 1998
 ATLS 1998
 Physical Medicine and Rehabilitation 2002
 Medical License 2002
 Michigan Medical License 1998

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/ **(Professional Societies):**

1. -American Medical Association
2. -American College of Rheumatology
3. -American Pain Society
4. -American Academy of Physical Medicine and Rehabilitation
5. -American Academy of EMG
6. -American Society of Neuroscience

(Award/Honors):

1. FDA -FDA Outstanding Service Award, 2017
2. FDA -USFDA Translational Medicine Working Group Award, 2016
3. FDA - USFDA PSP Working Group Award, 2015
4. FDA -FDA Group Recognition Award for Planning Committee for 1st
FDA Regenerative Medicine Forum 2014
5. FDA -FDA performance award on PMAP 2013
6. FDA -FDA AAV Adverse Event Working Group Award 2012
7. FDA - USFDA Cartilage Working Group Award, 2011
8. FDA -FDA Women Health Program Initiatives Award 2009
9. FDA -FDA Outstanding Service Award
10. FDA -FDA/CBER Continue Education Award
11. -Scholarship, American Pain Society
12. -Best Resident of Year, Medical college of Wisconsin 2001
13. -Best Resident of Year, Medical college of Wisconsin 2000

(Committ

2. CBER) -Cartilage Repair Working Group (Co-Chair for
3. Discussion) -Neurological Working Group (FDA Presentations and Round Table
4. -
5. -CBER/CDRH Planning Committee for
CDRH/CBER Articular Cartilage Seminar Series
6. -FDA/OWH Science Review
Committee (for research grants)
7. -FDA Project Advisory Group for Pregnancy
Labeling Mental Models Project
8. -CBER Planning Committee for New Reviewer
Training
9. -FDA pulmonary ad hoc review panel
10. -FDA Multi-center Bone Working Group
11. 510K -FDA 510K Working Group
12. -Planning Committee for FDA Cross-
Center Forum for Devices and Biologics 2010
13. -FDA Multi-center Regenerative Medicine
Working Group

(Advisory Committee / pre-decisional meetings):

1. Fibromyalgia -Fibromyalgia: Arthritis Advisory Committee, June 23,
2003
2. -Pain: Arthritis Advisory Committee, July 29-30, 2002
3. -Cellular Therapies for Repair and Regeneration
of Joint Surfaces Advisory Committee Meeting, March 03, 2005
4. 47 -47th FDAAC Planning Committee Chair, 2009
5. -USAMRMC Overview of DHP Clinical and Rehabilitative
Medicine Portfolio (Panel Member), May 04, 2011
6. -ICRS-FDA/CBER Liaison Meeting Regarding Product
Development of Cartilage Repair, FDA Planning Committee Chair, 2012

(Working Group for Regulatory Guidance Development):

1. -Guidance for Industry
Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Articular
Cartilage
2. -Guidance of for Industry Development program for Analgesics
3. -
for FDA-Sponsored Human Subject Research

(Teaching Activities):

1. -Teaching Faculty for the New Reviewer Training Program
in CBER, FDA

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2. BR301 Course -Advance Clinical Bioresearch monitoring
3. Hopkins University -Teaching Faculty for FDA Regulatory Science in Johns

(International Consultants) :

Group (USA/Canada) -Chronic Pain Clinical Trial Design Working

(Presentations):

-Introduction to FDA Biologic Product Review and Approval (*5th Chinese anti-cancer GCP Training Class, Beijing, 2010*)

-Introduction of Autologous Neo-Bladder Augment and Autologous Neo-Urinary Conduit (*FDA Cross-Center Forum for Devices and Biologics Used in Regenerative Medicine, White Oak, Maryland, 2010*)

(Publications):

A fbA Ab A A A fA A A Ab A
A A A A A A G A A N A A
A A N AN A A c A A
C A Ab A A Ab A fb A G A A
N A A
A A A A Ab AN A AA Ab A A A fA
Ab A A fb A A A A fb A fA A A A A
c A G A A N A A
A A AN AA A A fA A A A A A A
G A fA A fA A Ab A A A fA A A Ab A A
A A A A A A G A A N A A
A A A A A A A fA A Ab A c A A
A A A A A A A A A Ab A A
G A A N A A

6. **Michael Y. Yao**, Vasoactive Intestinal Peptide Retards Experimental Arthritis, *Rehab in Review* 2000, Harvard Medical School, Volume 8, Number 6.A

7. Lisa Patel, **Michael Y. Yao**, Joy H. Stein, A Rapid Method to target Rer gene in the Human ovary cDNA library by using DNA Chip Mapping Techniques, *Reproductive and Biotech* 1998, July 3, 19-24.A

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8. **Michael Y. Yao**, Larry Sutton, James C. Phillips, Modulation of Gene Expression after replication Deficient, Recombination Adenovirus 5-Mediated Gene transfer by the AD5 Vector, *Experimental Animals*, 1998, 14(8), 92-102.A

9. Peter K. Wilson, Carol Lerow, **Michael Y. Yao**, Larry Sutton, The Route of Administration is a Major Determinant of the Transduction Efficiency of Rat Brain by Adeno-TK Recombinants, *Gene therapy*, 1997, 26(11) 100-112A

10. Anna J. Janss, **Michael Y. Yao**, Allen Spilsky, James C. Phillips, Synergistic Cytotoxic Effects of Camptothecin and Topotecan with Alkylating Agents and Drug-specific and Dose-Dependent in Human Brain Tumor Cell Lines, *Oncology*, 1996, 18 (10) 56-58A

11. Qi Xiao, **Michael Y. Yao**, Simmete Tejjani-Butt, Acute Administration of a-Methylpara-Tyosine Alters Levels of Norepinephine Transporter mRNA in the Rats Brainstem, *Molecular Brain research*, 1995, 30 (1), 398-392A

12. James C. Phillips, **Michael Y. Yao**, James L. Smith, Adenovirus-Mediated Gene Therapy of Human Medulloblastoma Xenografts, in the Nude Rats, *Pediatric Oncology*, 1995, 24(12), 114-117A

13. **Michael Y. Yao**, James C. Phillips, Anna J. Janss, Neurotoxicity and Antitumor efficiency of Adenovirus-Mediated Gene Therapy in Medulloblastoma Xenografts in Nude Rats, *Experimental Oncology*, 1994, 3(9), 118-201A

Michael Y. Yao, Larry J. Simth, Karol Dick, Detecting Expression of P₅₃ on the CML Cell Lines by RNR-PCR in the Relapse Patients, accepted for Platform Presentation at International Society of Pediatric Oncology, Omaha, Nebraska, 1993 A

Larry J. Smith, Mary-Jean Dick, **Michael Y. Yao**, Karl Dick, Down Regulation of Expression of P₅₃ on the CML Cell Lines with Antisense Oligo in Vitro, *Blood*, 1992, 18(6), 178-181A

Michael Y. Yao, Daofang Ding, Application of Biostatistics and Epidemiology in the Clinical Studies, Chapter 20, In: *The Methods of Clinical Studies*, Edited by Daofang Ding, 1989, 399-446, Liaoning Press, Shenyang, P.R. China (Chinese)A

Michael Y. Yao, Baozhi, Sun, Application of Biostatistics in Medical Education and Management, Chapter 14, In: *Chinese Medical Education and Management*, Edited by Minzhang Chen, Co-Edited by Michael Y. Yao and Fong Yang, 1988, 208-268, GuJi Press, Beijing, P.R. China (Chinese)A

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