

# MAPS Places Fully Validated, Multi-Kilogram Synthesis of MDMA in the Public Domain

- MAPS and MAPS PBC have developed the first validated commercial synthetic process for producing multi-kilogram batches of MDMA under current Good Manufacturing Practices
- The availability of larger quantities of cGMP-compliant MDMA will facilitate ongoing clinical trials and provide for future therapeutic use following anticipated regulatory approvals
- Publication of this process establishes "prior art," contributing to MAPS' patient access strategy by making intellectual property public

MDMA is a promising psychedelic compound, currently placed by the Drug Enforcement Administration (DEA) in Schedule I of the Controlled Substances Act, that has been produced for legal research in small batches by certified laboratories. An increasing interest in clinical study of the 110-year-old compound, combined with anticipated regulatory approvals of MDMA-assisted therapies, necessitate the development of a multi-kilogram current Good Manufacturing Practices (cGMP) production process by the leading research sponsor, the [Multidisciplinary Association of Psychedelic Studies < http://maps.org >](http://maps.org) (MAPS), and trial organizer, [MAPS Public Benefit Corporation < https://mapspublicbenefit.com/>](https://mapspublicbenefit.com/) (MAPS PBC). "[Fully Validated, Multi-Kilogram cGMP Synthesis of MDMA < https://pubs.acs.org/doi/10.1021/acsomega.1c05520?ref=pdf >](https://pubs.acs.org/doi/10.1021/acsomega.1c05520?ref=pdf)" recently published in *ACS Omega*, a journal of the American Chemical Society, is the first paper to describe a fully validated cGMP synthesis of up to 5 kg (≈30,000 patient doses) of MDMA in a four-step process beginning with a non-controlled starting material.

“Based on our commitment to Open Science, adopted to promote scientific advances and patient access, MAPS Public Benefit Corporation (PBC) is sharing our manufacturing achievement for commercial production of MDMA with the scientific community. We are at the forefront of MDMA research, and our Open Science practices have been pushing the nascent field of psychedelic-assisted therapeutics forward for the last four decades.

[Jay B. Nair, Ph.D., P.M.P. < https://mapspublicbenefit.com/staff/jay-nair-ph-d-p-m-p/>](https://mapspublicbenefit.com/staff/jay-nair-ph-d-p-m-p/), lead author and MAPS PBC Head of Chemistry, Manufacturing, and Controls

The manufacture methods of MDMA at a laboratory scale were originally placed in the public domain by Alexander Theodore Shulgin, Ph.D., Ann Shulgin, and David E. Nichols, Ph.D., in 1991 with the publication of *PiHKAL: A Chemical Love Story* (1st Edition). With this peer-reviewed scientific publication, the manufacture methods for MDMA at industrial scale are also placed in the public domain. The chemical purity of the final product exceeded 99.9% in each of the four validation trials with an acceptable yield, which is a noteworthy accomplishment.

“[Promising clinical trial results < https://maps.org/news/media/9122-maps-phase-3-trial-of-mdma-assisted-therapy-for-ptsd-achieves-successful-results-for-patients-with-severe-chronic-ptsd >](https://maps.org/news/media/9122-maps-phase-3-trial-of-mdma-assisted-therapy-for-ptsd-achieves-successful-results-for-patients-with-severe-chronic-ptsd) have generated much interest in studying MDMA as a catalyst to therapy for PTSD and related conditions — and an increased demand for pharmaceutical-grade MDMA. This cGMP-compliant production process will supply the ongoing Phase 3 and investigator-initiated trials and will ameliorate existing supply constraints for the broader research community. As we approach our anticipated FDA approval in 2023, the availability of cGMP-compliant MDMA will be secured for future therapeutic use.

[Berra Yazar-Klosinski, Ph.D. < https://mapspublicbenefit.com/staff/berra-yazar-klosinski-ph-d/>](https://mapspublicbenefit.com/staff/berra-yazar-klosinski-ph-d/), contributing author and MAPS PBC Chief Scientific Officer

Nearly 4% of people worldwide will suffer from PTSD during their lifetime, including more than 8% of those who live in the U.S. PTSD can be a debilitating disorder, with symptoms including intrusive thoughts and memories, negative effects on thinking and mood, hyperarousal and reactivity, and avoidance. People with PTSD can experience much lower quality of life and relationships, related mental health conditions, and suicidality.

Clinical trials of MDMA-assisted therapy for PTSD sponsored by the non-profit [Multidisciplinary Association for Psychedelic Studies < https://maps.org/ >](https://maps.org/) (MAPS) and organized by [MAPS Public Benefit Corporation < https://mapspublicbenefit.com/ >](https://mapspublicbenefit.com/) (MAPS PBC) have been conducted with [specially trained < http://mapspublicbenefit.com/training >](http://mapspublicbenefit.com/training) mental health care providers. The U.S. Food and Drug Administration (FDA) granted [Breakthrough Therapy Designation < https://maps.org/wp-content/uploads/2017/08/2017.08.15-IND063384GrantBreakthroughTherapyDesignation1\\_Redacted.pdf >](https://maps.org/wp-content/uploads/2017/08/2017.08.15-IND063384GrantBreakthroughTherapyDesignation1_Redacted.pdf) to MDMA-assisted therapy for PTSD, acknowledging that it “may demonstrate substantial improvement over existing therapies” and agreeing to expedite its development and review. Regulators in Canada and the United Kingdom have granted similar designations.

NOTE

The safety and efficacy of MDMA-assisted therapy is currently under investigation. It has not yet been approved by the FDA, does not work for everyone, and carries risks even in therapeutic settings. These statements are no guarantee of future FDA approval or availability of MDMA-assisted therapy. These statements necessarily involve known and unknown risks and uncertainties, which may cause actual outcomes to differ materially from our projections.

###

MEDIA CONTACT

Betty Aldworth, Director of Communications  
[maps.org/newsroom < http://maps.org/newsroom >](https://maps.org/newsroom) or [media@maps.org](mailto:media@maps.org)  
831-429-6362 ext 303

ABOUT [MAPS < http://maps.org >](http://maps.org)

Founded in 1986, MAPS is a 501(c)(3) non-profit research and educational organization that develops medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana. MAPS is sponsoring the most advanced psychedelic therapy research in the world: Phase 3 clinical trials of MDMA-assisted therapy for PTSD. Since its founding, MAPS has raised over \$130 million in donations and grants for psychedelic and marijuana research and education and has earned both the [GuideStar Platinum Seal of Transparency < https://www.guidestar.org/profile/59-2751953 >](https://www.guidestar.org/profile/59-2751953) and a [4-Star Rating from Charity Navigator < https://www.charitynavigator.org/ein/592751953 >](https://www.charitynavigator.org/ein/592751953).

ABOUT [MAPS PUBLIC BENEFIT CORPORATION < http://mapspublicbenefit.com >](http://mapspublicbenefit.com) (MAPS PBC)

MAPS Public Benefit Corporation (MAPS PBC) catalyzes healing and well-being through psychedelic drug development, therapist training programs, and sales of prescription psychedelics while prioritizing public benefit above profit. Founded in 2014, MAPS PBC is a wholly-owned subsidiary of the Multidisciplinary Association for Psychedelic Studies (MAPS), a 501(c)(3) non-profit organization.